HOLOGIC INC
Form 10-K
November 28, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended: September 29, 2012

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: 0-18281

Hologic, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-2902449**
(State or Other Jurisdiction of	**(IRS Employer**

Incorporation or Organization) **Identification No.)**

35 Crosby Drive, Bedford, Massachusetts 01730

(Address of Principal Executive Offices) (Zip Code)

Registrant s Telephone Number, Including Area Code (781) 999-7300

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	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: Rights to Purchase Preferred Stock

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

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 x 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer x	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 Act). Yes ¨ No x

The aggregate market value of the registrant s Common Stock held by non-affiliates of the registrant as of March 24, 2012 was $5,549,871,525 based on the price of the last reported sale on the Nasdaq Global Select Market on that date.

As of November 20, 2012, there were 266,770,196 shares of the registrant s Common Stock, $.01 par value, 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 29, 2012 are incorporated into Part III (Items 10, 11, 12, 13 and 14) of this Annual Report on Form 10-K where indicated.

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HOLOGIC, INC.

ANNUAL REPORT ON FORM 10-K

For the Fiscal Year Ended September 29, 2012

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements involve known and unknown risks, uncertainties and other factors which may cause our or our industry s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding:

- the effect of the continuing worldwide macroeconomic uncertainty on our business and results of operation;
- the coverage and reimbursement decisions of third-party payors 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 operation;
- the anticipated impact of the U.S. excise tax on the sale of most medical devices, currently scheduled to become effective on January 1, 2013, on our business and results of operation;
- the impact and anticipated benefits of the acquisition of Gen-Probe and the challenges associated with successfully integrating and operating the Gen-Probe business;
- the impact and anticipated benefits of other recently completed acquisitions and acquisitions we may complete in the future;
- our ability to consolidate certain of our manufacturing operations on a timely basis without disrupting our business and to achieve anticipated cost synergies in connection therewith;
- our goal of expanding our market positions;
- the development of new competitive technologies and products;
- regulatory approval and clearances for our products;
- production schedules for our products;
- the anticipated development of our markets and the success of our products in these markets;
- the anticipated performance and benefits of our products;

business strategies;

estimated asset and liability values;

the impact and costs and expenses of any litigation we may be subject to now or in the future;

our compliance with covenants contained in our indebtedness;

anticipated trends relating to our financial condition or results of operations; 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, expects, plans, anticipa believes, estimates, projects, predicts, potential and similar expressions intended to identify forward-looking statements. These statements ar 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: Adiana, Affirm, APTIMA, APTIMA COMBO 2, Aquilex, ATEC, Celero, Cervista, C-View, Dimensions, Eviva, Fluoroscan, Gen-Probe, Healthcome, Interlace, Invader, LIFECODES, LORAD, MammoPad, MammoSite, MultiCare, MyoSure, NovaSure, PANTHER, PROCLEIX, PreservCyt, QDR, Rapid fFN, Sahara, SecurView, Selenia, Sentinelle, Serenity, StereoLoc, Suresound, TCT, ThinPrep, THA, THS, TIGRIS, TLI IQ, and Trident.

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PART I

Item 1. Business

Overview

We are a leading developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women. Our core business units are focused on breast health, diagnostics, GYN surgical, and skeletal health. We sell and service our products through a combination of direct sales and service forces and a network of independent distributors and sales representatives.

Our breast health products include a broad portfolio of breast imaging and related products and accessories, including digital and film-based mammography systems, magnetic resonance imaging, or MRI, breast coils, computer-aided detection, or CAD, for mammography and MRI, minimally invasive breast biopsy devices, breast biopsy site markers, breast biopsy guidance systems, breast imaging comfort pads, and breast brachytherapy products. Our most advanced breast imaging platform, Dimensions, utilizes a new technology called tomosynthesis to produce three dimensional, or 3D, images, as well as conventional two dimensional, or 2D, full field digital mammography images. In the U.S., our Dimensions product was approved in December 2008 by the Food and Drug Administration, or FDA, for providing conventional 2D images. In February 2011, we received approval from the FDA to enable the 3D tomosynthesis capability of our Dimensions system.

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. Our molecular diagnostics products include our APTIMA family of assays, our proprietary Invader chemistry and advanced instrumentation (PANTHER, TIGRIS and HTA). The APTIMA family of assays is used to detect the common sexually transmitted diseases, or STDs, chlamydia and gonorrhea, certain high-risk strains of the human papillomavirus, or HPV, and Trichomonas vaginalis, the parasite that causes trichomoniasis. Our Invader chemistry comprises molecular diagnostic reagents used for a variety of DNA and RNA analysis applications, including Cervista HPV high risk, or HR, and Cervista HPV 16/18 products to assist in the diagnosis of HPV, as well as other products to diagnose cystic fibrosis, cardiovascular risk and other diseases. Our diagnostics products also include the ThinPrep System, which is primarily used in cytology applications such as cervical cancer screening, and the Rapid Fetal Fibronectin Test, which 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 the human immunodeficiency virus, or HIV, the hepatitis C virus, or HCV, the hepatitis B virus, or HBV, and the West Nile virus, or WNV, in donated human blood. These blood screening products are marketed worldwide by our blood screening collaborator, Novartis Vaccines and Diagnostics, Inc., or Novartis, under Novartis trademarks.

Our GYN surgical products include the NovaSure Endometrial Ablation System, or NovaSure, and the MyoSure Hysteroscopic Tissue Removal System, or MyoSure. The NovaSure system involves a minimally invasive procedure for the treatment of heavy menstrual bleeding. The MyoSure system is a tissue removal device that is designed to provide transcervical or incision-less removal of fibroids and polyps within the uterus.

Our skeletal health products include dual-energy X-ray bone densitometry systems, an ultrasound-based osteoporosis assessment product, and our Fluoroscan mini C-arm imaging products.

We were incorporated in Massachusetts in October 1985 and reincorporated in Delaware in March 1990.

Recent Events

Acquisition of Gen-Probe Incorporated

On August 1, 2012, pursuant to the terms of the Agreement and Plan of Merger, dated April 29, 2012, referred to as the merger agreement, we completed our acquisition of Gen-Probe. Under the terms and conditions of the merger agreement, at the effective time and as a result of the acquisition, each share of common stock of Gen-Probe issued and outstanding immediately prior to the effective time of the acquisition was cancelled and converted into the right to receive $82.75 in cash. In addition, all outstanding restricted shares, restricted stock units, and performance shares and all stock options granted prior to February 8, 2012 were cancelled and converted into the merger consideration based upon an $82.75 per share price. Stock options granted after February 8, 2012 were cancelled and converted into stock options to acquire shares of Hologic common stock determined by a conversion formula defined in the merger agreement. The total purchase price was approximately $3.97 billion, which was funded through available cash and financing consisting of senior secured credit facilities and Senior Notes discussed below.

Concurrent with the closing of the Gen-Probe acquisition, on August 1, 2012, we and certain domestic subsidiaries entered into a credit and guaranty agreement with Goldman Sachs Bank USA in its capacity as administrative and collateral agent, and the lenders party thereto, pursuant to which we obtained senior secured financing totaling $2.8 billion, consisting of term loans in the aggregate principal amount of $2.5 billion and an undrawn $300 million revolving credit facility. Also on August 1, 2012, we completed a private placement of $1.0 billion aggregate principal amount of our 6.25% Senior Notes due August 1, 2020.

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Gen-Probe, headquartered in San Diego, California, is a leader in molecular diagnostics products and services that are used primarily to diagnose human diseases, screen donated human blood and test transplant compatibility. Gen-Probe s results of operations are reported within our diagnostics segment from the date of acquisition.

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 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.

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: Breast Health, Diagnostics, GYN Surgical and Skeletal Health. Financial information concerning these segments is provided in Note 15 to our audited consolidated financial statements contained in Item 15 of this Annual Report.

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 3D image acquisition and display. When operating in 3D 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, revealing breast tissue from a 3D perspective. We believe that by allowing the clinician to review breast tissue in three dimensional space, 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. In the U.S., our Dimensions product had previously been approved by the FDA for providing conventional 2D images. In February 2011, we received approval from the FDA to enable the 3D tomosynthesis capability of our Dimensions system. Our clinical results for the 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.

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C-View System

In November 2011, we announced the commercial release of our C-View product, which is a 2D image that is mathematically synthesized from the data within a 3D 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 at a slightly longer compression time than a conventional mammogram. In order to further reduce breast compression time from the current combo exam, the C-View product allows for the mathematical construction of a 2D image from the 3D data, without the need for an actual 2D exposure. Elimination of the 2D exposure reduces the compression time and patient dose. Our C-View software is approved for sale throughout the European Economic Area and in other countries recognizing the CE Mark. During the third quarter of fiscal 2012, we submitted a pre-market supplement application to the FDA for approval to sell this product in the United States. On October 24, 2012, the Radiological Devices Panel of the FDA voted that the expanded indications for use of our Dimensions 3D system to allow our C-View synthesized 2D images in place of traditional 2D images in breast cancer screening is safe, effective and the benefits outweigh the risks. Sale of the 3D version of this system in the United States remains subject to FDA approval.

Selenia

The Selenia product family, our original full field digital mammography platform, has a number of additional features designed to improve image quality and patient throughput. The open architecture of the system s design provides for full integration with existing enterprise Picture Archiving and Communications Systems, or PACS, and Radiology Information Systems, or RIS. The Selenia product family includes the Selenia base configuration, the Selenia S configuration (a screening-only configuration), the Selenia Performance (a lower cost alternative to the Selenia base configuration) and the Selenia Encore (refurbished units), each of which offer customers varying performance capabilities and product costs.

Healthcome Mammography Products

In July 2011, we completed our acquisition of Beijing Healthcome Technology Company, Ltd., a privately-held manufacturer of medical equipment located in Beijing, China. Healthcome manufactures analog mammography products targeted to lower tier hospital segments in China. Additionally, Healthcome had been collaborating with our research and development team to integrate our selenium digital detector with the Healthcome mammography system. On December 21, 2011, we received State Food and Drug Administration, or SFDA, approval in China for our Serenity digital mammography system. We began selling this product in China in the second quarter of fiscal 2011, and intend to commercialize it throughout Asia and potentially other emerging markets in the future.

Screen-Film Mammography Systems

Our screen-film mammography systems include our LORAD M-IV system. These systems are less expensive than our digital systems and further offer customers varying performance capabilities and product costs.

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 and MRI products. Mammography CAD is used by radiologists as a second pair of eyes when reading a woman s mammogram. Use of this technology provides reviewers with the potential to detect findings that might otherwise be overlooked during the review process, thus potentially increasing cancer detection. We also market an MRI CAD 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 M-IV series of screen-film mammography systems and our Selenia full field digital mammography 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.

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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 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 vacuum-assisted breast biopsy device can be used under all standard imaging guidance modalities (stereotactic x-ray, ultrasound, MRI and molecular breast imaging) whereas our Eviva vacuum-assisted breast biopsy device is used exclusively under stereotactic x-ray guidance. In addition to ATEC and Eviva products, we also offer the Celero device, a non-tethered (no separate console), vacuum-assisted, spring-loaded, disposable core biopsy device which is used exclusively under ultrasound-guidance. All of our breast biopsy devices have been designed to accommodate a broad spectrum of patients as well as hard-to-reach lesions in the axilla, near the chest wall, near implants or behind the nipple.

Breast Brachytherapy Products

The MammoSite Radiation Therapy System is a breast brachytherapy technology that offers accelerated partial breast irradiation, or APBI, therapy to treat breast cancer. A MammoSite balloon, which is inserted into the surgical cavity remaining after a lumpectomy, delivers a 5-day course of concentrated radiation to the tissue most likely to contain residual cancerous cells following surgery, while reducing radiation exposure to adjacent healthy tissue. The MammoSite ML system allows radiation oncologists to shape the radiation dose for typical cases and treat patients who are otherwise not appropriate candidates for traditional brachytherapy. The MammoSite ML device has a central lumen, similar to the original MammoSite device, and three offset lumens parallel to the central lumen. In addition to allowing greater flexibility in radiation treatment planning, the use of a multiple-lumen device typically results in a higher reimbursement rate.

MammoPad Breast Cushion

Our mammography related products include a proprietary MammoPad breast cushion. The MammoPad cushion is designed to reduce the discomfort women often experience during mammography. The cushion s grip-like surface also holds breast tissue in place to improve breast positioning. The radiolucent cushion does not interfere with image quality and can be used with all of our mammography systems.

Photoconductor Coatings

Our Hologic Hitec-Imaging GmbH subsidiary is our sole supplier of the amorphous selenium photoconductor coatings employed in our Selenia and Dimensions full-field digital mammography detectors. Hitec-Imaging also develops, manufactures, and sells non-medical selenium and organic photoconductor materials for use in a variety of other electro photographic applications, including copying and printing. In the third quarter of fiscal 2012, we finalized our decision to move our selenium panel coating production line to our facility in Newark, Delaware. We expect this transfer to be completed in the second half of fiscal 2013.

Sentinelle Medical MRI Coils and Workstation

Our Sentinelle Medical subsidiary develops, manufactures and markets a suite of high performance breast MRI coils. MRI coils are antenna receivers that are used to collect radio-frequency information emitted from a patient during an MRI procedure. These signals are fed into the MRI magnet system which produces a 3D image from the information. The coils are tuned to specific frequencies and positioned in calculated geometries to provide high quality signal to noise performance of the MRI system. The coils are integrated into various MRI scanning systems, and employ a unique variable coil geometry to obtain improved image quality by positioning the coils in close proximity to the tissue. The coil is not fixed and allows the healthcare provider to adjust positioning to each patient s unique anatomy. This close positioning results in higher signal to noise ratio and improved image resolution. The improved resolution also enhances guidance for biopsy targeting. We are also developing coils for other indications, and in the fourth quarter of fiscal 2011, we received FDA 510(k) clearance for our new prostate coil, the Sentinelle Endo Coil Array for pelvic imaging including the prostate, cervix, colon and the surrounding tissues in the pelvis. With a similar profile to a transrectal ultrasound probe, this two-channel endo coil array is designed to acquire images in a manner that should help align radiologists and urologists in the diagnosis and treatment of prostate cancer. Commercialization of this product commenced in the first quarter of fiscal 2012. In addition, we sell an MRI CAD workstation designed to simplify workflow and improve diagnostic capabilities.

Trident Specimen Radiography System

In August 2011, we received FDA 510(k) clearance for our new Trident specimen radiography system. The Trident specimen radiography system is a cabinet x-ray system used to provide digital images of surgical and core biopsy specimens to verify that the correct tissue has been excised during surgery or a breast biopsy procedure. The Trident system incorporates our amorphous selenium based detector technology. It is a compact and portable unit designed to be used in the same room or close to where breast surgery or biopsy procedures take place. Performing

verification in the same room as the procedure or nearby can improve workflow and reduce the time the patient needs to be undergoing a procedure or surgery. Commercialization of this product commenced in the first quarter of fiscal 2012.

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Diagnostic Products

APTIMA Family of Assays for Women s Health

As a result of our recent acquisition of Gen-Probe, we now offer our APTIMA family of assays that includes the APTIMA Combo 2 assay for the simultaneous detection of chlamydia and gonorrhea, the standalone APTIMA CT and APTIMA GC assays for the detection of Chlamydia and gonorrhea, respectively, the APTIMA HPV assay for the detection of 14 sub-types of high-risk HPV associated with cervical cancer, and the APTIMA Trichomonas assay for the detection of *Trichomonas vaginalis*, the parasite that causes trichomoniasis. Our APTIMA products integrate our patented transcription-mediated amplification, or TMA, technology, target capture technology, and our patented 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. 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 a magnetic separation device 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. Our patented TMA technology is designed to overcome problems faced by other target amplification 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 30 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.

Instrumentation, including for the APTIMA Family of Assays. We have developed and continue to develop instrumentation and software designed specifically for performing certain of our diagnostic assays, including the APTIMA family of assays and the PROCLEIX family of assays in the blood screening market. We also provide technical support and instrument service to maintain these instrument systems in the field. By placing our proprietary instrumentation in laboratories and hospitals, we can establish a platform for future sales of our diagnostic assays.

Our instrumentation includes the TIGRIS system, an integrated, fully-automated testing instrument for high-volume laboratories which is approved for use with a number of our APTIMA and PROCLEIX assays, the PANTHER instrument system, an integrated, fully automated testing instrument for low- to mid-volume laboratories, and our semi-automated direct tube sampling (DTS) instruments which are used to run a number of infectious disease and blood screening assays. The PANTHER instrument was CE-marked and launched in Europe for diagnostic use in the fourth quarter of 2010. In August 2011, Health Canada granted us a medical device license to use the PANTHER system to run our APTIMA Combo 2 assay in Canada. In addition, in May 2012 the FDA cleared the PANTHER system to run our APTIMA Combo 2 assay for the detection of chlamydia and gonorrhea in the United States. We are also developing the PANTHER system for use in the blood screening market as part of our blood screening collaboration with Novartis and the PANTHER system and the Ultrio Elite blood screening assay were CE marked in June 2012. We also sell PANTHER systems to Roka Bioscience, Inc. for use in certain industrial markets. In addition, we have recently initiated development programs to add real-time PCR capabilities to a new instrument system that also incorporates the capabilities of our first-generation PANTHER system and to develop a new, standalone instrument to further automate molecular testing from liquid-based cytology specimens.

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In October 2012, we received FDA approval of our APTIMA HPV 16 18/45 Genotype Assay for use on our TIGRIS system. We expect to begin commercialization during the first quarter of fiscal 2013.

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, polymerase chain reaction (PCR) or real-time PCR products.

Cervista HPV Tests. HPV is the most common sexually transmitted disease in the U.S. and is recognized as the cause of most cervical cancer. We offer two HPV tests using the Invader chemistry: the Cervista HPV HR and the Cervista HPV 16/18. These tests employ our proprietary Invader technology and are performed out of the ThinPrep PreservCyt collection vial. Cervista HPV HR is a qualitative test used for the detection of DNA from fourteen high-risk HPV types responsible for most cervical disease. The Cervista HPV 16/18 test is a qualitative test used for the detection of DNA from HPV types 16 and 18, the types that cause approximately 70% of cervical cancer.

Both our APTIMA and Cervista HPV HR tests have been approved for triaging women with undetermined cervical cytology and co-testing with cervical cytology for women 30 years and older. Our Genotype assays have been approved to be used adjunctively with the APTIMA and Cervista HPV HR tests in combination with cervical cytology to assess the presence of high risk HPV types, as well as to triage women with undetermined cervical cytology results along with our HPV tests. Our APTIMA and Cervista HPV tests are targeted to meet a broad spectrum of customer needs across both centralized and decentralized segments of the clinical laboratory markets.

In December 2011, we announced that the FDA approved our Cervista High Throughput Automation System, which we refer to as the HTA system, for use with our Cervista HPV HR test. The Cervista HTA system automates the DNA extraction and detection steps of the Cervista HPV HR test and allows for significantly less manual time during processing. This product was launched in January 2012.

Other Invader Products. Other current clinical diagnostic offerings based upon our Invader chemistry include the following:

- A molecular assay to identify patients who may be at increased risk of adverse reaction to the chemotherapy drug Camptosar (irinotecan) by detecting and identifying specific mutations in the UGT1A1 gene that have been associated with that risk.

- Products to assist in the diagnosis of cystic fibrosis, cardiovascular risk and other diseases.

In addition, we sell products to the Agricultural Biotechnology market. We also have an active out-licensing and partner program in areas outside of our core business that allows us to further realize the value of our Invader chemistry platform.

ThinPrep System

The ThinPrep System is the most widely used method for cervical cancer screening in the United States. If detected in the pre-cancerous stage, most cervical cancer cases are preventable. The ThinPrep System consists of any one or more of the following: the ThinPrep 2000 Processor, ThinPrep 3000 Processor, ThinPrep 5000 Processor, ThinPrep Imaging System, and related reagents, filters and other supplies, such as the ThinPrep Pap Test and our proprietary ThinPrep PreservCyt Solution. Our ThinPrep 5000 Processor has been launched for full use, as described below, outside of the U.S. but is limited to non-gynecological screening samples in the U.S.

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 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 and locates areas of interest for review. By directing the cytotechnologist to areas of interest on a slide, the system may increase a cytology laboratory s screening productivity and diagnostic accuracy. In Europe, where laboratories tend to be smaller, processing fewer tests, we also offer a lower throughput imaging device, which we introduced in September 2009 to assist in the detection of cervical cancer.

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

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Rapid Fetal Fibronectin Test

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

Procleix Family of Assays for Blood Screening

As a result of our acquisition of Gen-Probe, we develop and manufacture the PROCLEIX family of assays, which are marketed and sold worldwide by Novartis, our blood screening collaborator, under Novartis trademarks. The PROCLEIX family of assays includes the HIV-1/HCV assay which simultaneously detects HIV type-1, or HIV-1, and HCV in donated blood, plasma, organs and tissues, the Ultrio and Ultrio Plus assays which simultaneously detect HIV-1, HCV and 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, and the WNV assay which detects West Nile Virus in donated blood, plasma, organs and tissues.

In June 2012, our Ultrio Elite blood screening assay for the detection of HIV-1, HIV-2, HBV and HCV received a CE mark, which authorizes the sale and marketing of the Ultrio Elite assay in the European Union. The Ultrio Elite assay runs on our PANTHER instrument system.

Infectious Disease and Virology Products

As a result of our acquisition of Gen-Probe, we now offer a number of products in the infectious disease space, including a number of assays for the detection of certain respiratory and gastrointestinal diseases as a result of our acquisition of Prodesse, Inc. in October 2009. Our infectious disease products include multiplex real-time PCR assays to detect and differentiate various influenza types and viruses, a real-time PCR assay to detect the Tuberculosis pathogen, and a rapid assay for the direct detection of *Streptococcus pyogenes* in one hour from a throat swab.

In virology, nucleic acid test assays can be used to detect viral DNA or RNA in a patient sample. These tests can be qualitative, meaning that the tests simply provide a yes-no answer for the presence or absence of the virus, or quantitative, meaning that the test determines the quantity of virus in the patient sample. We offer APTIMA assays for the qualitative detection of HIV-1 and HCV. In addition, we sell analyte specific reagents for quantitative HCV testing in the United States through our collaboration with Siemens Healthcare Diagnostics, Inc., or Siemens. We are developing quantitative viral assays to run on our PANTHER instrument system.

Prostate Oncology

The field of NAT-based cancer diagnostics is an emerging market as new markers that correlate to the presence of cancer continue to be discovered. According to the Prostate Cancer Foundation, prostate cancer is the most common non-skin cancer in the United States, affecting an estimated one in six men. Through our acquisition of Gen-Probe, we acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure, Inc., or DiagnoCure, in November 2003. In addition, in April 2006, we entered into a license agreement with the University of Michigan for exclusive worldwide rights to develop diagnostic tests for genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue.

In November 2006, we CE-marked our PROGENSA PCA3 assay, allowing it to be marketed in Europe. This gene-based test is designed to detect the over-expression of PCA3 mRNA in urine. Studies have shown that, in greater than 90% of prostate cancer cases, PCA3 is highly over-expressed (65-fold on average) in prostate cancer cells compared to normal cells, indicating that PCA3 may be a useful biomarker for prostate cancer. In February 2012, the FDA approved our PROGENSA PCA3 assay for sale and marketing in the United States. The PROGENSA PCA3 assay is to be used, in conjunction with other patient information, to help guide repeat biopsy decisions for men who have had one or more prior negative biopsies. The test has been approved for use on our semi-automated DTS instrument systems.

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Transplant Diagnostics

As a result of our acquisition of Gen-Probe, our transplant diagnostics business, which we refer to as our LIFECODES business, now comprises our human leukocyte antigen, or HLA, products and related assays. HLA testing, also known as HLA typing or tissue typing, identifies antigens on white blood cells that determine tissue compatibility for organ transplantation (that is, histocompatibility testing). HLA typing is used to provide evidence of tissue compatibility. The antigens expressed on the surface of the lymphocytes of the recipient are matched against those from various donors. HLA typing is performed for kidney, bone marrow, liver, pancreas, and heart transplants. HLA testing is also performed to reduce the probability of transplant rejection and for the ongoing management of transplant recipients.

We currently offer a range of multiplexed assays in the field of transplant diagnostics pursuant to our development and supply agreement with Luminex Corporation. We also offer a range of HLA antibody detection products under our LIFECODES brand, as well as a number of other HLA-related testing products, including serological typing trays, enzyme immunoassays, and a range of molecular typing products for donor-recipient matching and patient monitoring.

GYN Surgical Products

NovaSure

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

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

MyoSure

The MyoSure system is designed to provide efficient and effective hysteroscopic removal of fibroids located just below the lining of the uterus as well as uterine polyps. 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. Also, minimal tissue destruction makes the MyoSure system a good choice for women seeking to preserve uterine form and function.

The MyoSure system consists of a tissue removal device, control unit, and hysteroscope. The 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.

Towerfree Hysteroscopy System

The Towerfree Hysteroscopy System, or THS, is a hysteroscopy system that allows for visualization and inspection of the uterine cavity. The THS instrumentation was designed specifically for the gynecologist s office, providing a compact and simple platform for uterine diagnosis and minor intrauterine operative procedures. The system consists of a video platform and hysteroscope instrumentation. The components of the THS system (including a light source, camera, monitor and image capture system) have been integrated into a compact and portable unit. This is different from traditional hysteroscope systems, which are generally offered as separate units and require a large cart and significant footprint within the exam room.

The THS instrumentation provides versatility in performing minor operative procedures intended to expand the utilization of the system and support the see and treat benefit of hysteroscopy. The operative hysteroscope has a continuous flow, single-piece design for simple assembly and operation. It has been designed to enhance procedural conditions for the physician as well as patient comfort. The instrument channel accommodates instruments that may be used to grasp or remove tissue. For those customers who want to perform diagnostic hysteroscopy, THS offers a small diameter single flow sheath, which reduces the need for cervical dilation and provides a tool for quick and simple visualization of

the uterine cavity.

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Aquilex Fluid Control System

The Aquilex fluid control system is a product that measures the inflow and outflow of fluid from the patient during hysteroscopic procedures and is designed to reduce procedure and anesthesia time associated with hysteroscopic procedures while providing high quality visualization to the surgeon.

Adiana Permanent Contraception System

The Adiana system is a non-invasive procedure for permanent female contraception that requires no incisions and can be performed in the doctor s office using local anesthesia. In the second quarter of fiscal 2012, we decided to cease manufacturing, marketing and selling our Adiana system. We determined that the product was not financially viable and would not become so in the foreseeable future.

Skeletal Health Products

QDR 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 QDR x-ray bone densitometers incorporate dual-energy x-ray technology to precisely assess bone density of the most important fracture sites, the spine and hip. Since our commercial introduction of the first bone densitometer employing dual-energy x-ray technology in 1987, we have continually improved upon our technology, and the use of dual-energy x-ray technology has become and remains a leading bone densitometry assessment tool. We offer a range of bone densitometers with various features and options to address the requirements of our diverse customer base.

Sahara Clinical Bone Sonometers

We have developed and sell a relatively low-cost, lightweight, portable ultrasound bone analyzer, which assesses the bone density of the heel that can assist in initial screening for osteoporosis.

Mini C-arm Imaging

We manufacture and distribute Fluoroscan mini C-arm imaging systems. Mini C-arms provide low intensity, real-time x-ray imaging, with high-resolution images at radiation levels and at a cost below those of conventional x-ray and fluoroscopic equipment. Mini C-arm systems are used primarily by orthopedic surgeons to perform 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 2012, 2011 and 2010, no customer accounted for more than 10% of our consolidated revenues. With respect to our Diagnostics segment, as a result of our acquisition of Gen-Probe, we expect that one customer, Novartis, will account for more than 10% of annual revenues of that segment in the future. In fiscal 2012, 2011 and 2010, foreign sales accounted for approximately 27%, 24% and 21% of our product sales, respectively. See Note 15 to our consolidated financial statements contained in Item 15 of this Annual Report for geographical information concerning those sales.

U.S. Marketing and Sales

Our U.S. Breast Health and Skeletal Health sales force is comprised of full line modality account managers selling mammography and bone densitometry products, assisted by women s health product specialists and osteoporosis sales specialists. Our biopsy and MRI sales specialists, who often work together with account managers, sell breast biopsy devices and breast biopsy site markers to radiologists and breast surgeons, as well as custom MRI coils and patient positioning systems to radiologists. Our territory sales specialists sell both our MammoSite and breast biopsy and site marker products and target breast surgeons and radiation oncologists. In addition to our MRI sales specialists, our Sentinelle Medical MRI business also supports the original equipment manufacturers, or OEM, channel with product specialists and sales support. 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, or IDNs, 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 our products.

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Our U.S. Diagnostics and GYN Surgical sales forces focus on clinical laboratories, healthcare providers, and third-party payors. A critical element of our strategy in the United States 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 Diagnostics sales force includes both cytology and molecular specialists focusing on selling to a broad range of laboratories. In addition, our Diagnostics sales specialists call exclusively on OB/GYN offices, while our GYN Surgical sales force targets GYN surgeons in both hospital and office settings.

International Marketing and Sales

We sell our breast health and skeletal health products in international markets through a network of independent distributors and sales representatives, as well as a direct sales and service force in Belgium, the UK, Australia and most recently in China for our Healthcome products. We offer our products in Europe, the Middle East, Africa, South Asia, Latin America, and Pacific Rim countries, including China, Japan, Australia, South Korea, Thailand and Taiwan, through local sales representatives in select countries and through distributors in those territories.

Our Diagnostics and GYN Surgical products are marketed outside of the United States by direct operations in Canada, Europe, Australia, China and Hong Kong. We established these operations to manage sales, service, training and distribution in the Canadian, European and Asia/Pacific markets. We also utilize a network of third-party distributors in various other countries throughout the world. We believe that in order to effectively market our current products and any other new products and applications on a worldwide basis, we will need to continue to increase our international marketing, sales, and service capabilities.

Service

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 or components. We also offer service contracts to our customers 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. In addition, many of our competitors and potential competitors are larger and have greater financial resources than we do. Some of the companies with whom we compete have or may have more extensive research, sales, marketing and manufacturing capabilities and significantly greater technical resources than we do, and may be better positioned to continue to improve their technology in order to compete in an evolving industry. Competitors may develop superior products or products of similar quality for sale at the same or lower prices. Moreover, our products could be rendered obsolete by new industry standards or changing technology. We can give no assurance that we will be able to compete successfully with existing or new competitors.

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 could put 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 attributes that are most important and cost-effective to customers. This includes, but is 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.

Breast Health. Our mammography and related products and subsystems compete on a worldwide basis with products offered by a number of competitors, including GE, Siemens, Philips (who recently acquired Sectra), Planmed, Agfa, Carestream Health, Fuji, IMS Giotto, and Toshiba. In the U.S., our full field digital mammography systems compete with digital mammography systems from GE, Siemens, Fuji, Giotto, 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. Our 3D tomosynthesis systems compete in certain countries outside of the U.S. with 3D tomosynthesis systems developed by Siemens, Giotto, and Philips. We also understand that GE is developing a 3D tomosynthesis system. Although

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we understand that certain of our competitors, including GE and Siemens, are developing 3D tomosynthesis systems for commercial use in the U.S., there are no 3D tomosynthesis systems, other than our Dimensions system, that have been approved for use in the U.S. by the FDA. Any such use will require pre-market approval, or PMA, by the FDA. As a result, in the U.S. our 3D tomosynthesis systems currently compete primarily with lower cost 2D digital mammography systems.

Our Sentinelle Medical MRI breast coils compete primarily with products sold by Invivo, which was acquired by Philips in 2006, to end users and original equipment manufacturers, as well as other smaller third-party coil designers and the original equipment manufacturers themselves.

The primary competitors for our breast biopsy product line are Devicor Medical Products, which acquired the Mammotome product line from Ethicon, and C.R. Bard, which recently acquired SenoRx. In addition, other competitors include CareFusion, Sanarus and Intact Medical.

Our MammoSite systems face competition from companies also selling accelerated partial breast irradiation products, including C.R. Bard and Cianna Medical, as well as from other technologies, such as treatments using external beam, whole breast radiation, which has longer-term data on patient outcomes. Alternative radiation therapy methods, such as intraoperative radiation therapy, are being used by some institutions; however, such alternative methods have not yet achieved widespread commercial use. We believe that the breast brachytherapy market has and will continue to experience challenges including downward pressure on procedure volumes due to the continuing adverse economic environment and current trends in breast cancer management, as well as competitive pricing pressures and competition from existing and alternative new technologies.

Diagnostics. Our ThinPrep liquid-based cytology product faces direct competition in the United States primarily from Becton, Dickinson and Company, 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 off-market (non-FDA approved) tests, since fewer regulatory barriers exist in most international markets as compared to the United States.

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 United States. Internationally, our Rapid Fetal Fibronectin Test competes with Actum Partus manufactured by Alere. 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. These companies may have or develop products competitive with those offered by us. 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. Such laboratory-developed tests may not be subject to the same clinical trial and FDA submission requirements as our products.

In the global clinical diagnostics market, we compete with several companies offering alternative technologies to our diagnostic products including Abbott Laboratories, Siemens, Becton, Dickinson and Company, bioMérieux, Cepheid, Life Technologies Corporation, Luminex Corporation, Qiagen, Roche Diagnostics Corporation, and Siemens. Specifically, in the U.S. our APTIMA Combo 2 tests compete against Becton, Dickinson and Roche, and our APTIMA HPV tests compete with tests marketed by Qiagen, which received FDA approval in 1999, and Roche Diagnostics, which received PMA approval for a high risk HPV test and 16/18 test in 2011.

In the market for blood screening products, our primary competitor is Roche, which received FDA approval of its first PCR-based nucleic acid tests for blood screening in December 2002. We also compete with assays developed internally by blood screening centers and laboratories based on PCR technology. In the future, our blood screening products may compete with viral inactivation or reduction technologies and blood substitutes.

Novartis retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening using nucleic acid testing. Prior to its acquisition by Novartis, Chiron Corporation, or Chiron, granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron also granted HIV and HCV licenses in the clinical diagnostics field to Bayer Healthcare LLC (now Siemens), together with the right to grant certain additional HIV and HCV sublicenses in the field to third parties. If Novartis or Siemens grant additional licenses, further competition will be created for sales of HCV and HIV assays and these licenses could affect the prices that can be charged for certain of our products.

GYN Surgical. Our NovaSure system currently faces direct competition from Johnson & Johnson, Boston Scientific and CooperSurgical, each of which currently markets an FDA approved second generation endometrial ablation device for the treatment of excessive menstrual bleeding. In

addition to these devices, we also compete with alternative treatments to our NovaSure system, such as drug therapy, IUDs, hysterectomy, dilation and curettage and rollerball ablation. Internationally our products compete with drug therapy and first generation rollerball technology, as well as other endometrial ablation devices, including Johnson &

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Johnson s Thermachoice, Boston Scientific s HTA, and two other relatively small companies that market products that are not FDA approved. 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 and Smith & Nephew s TruClear tissue morcellator. The MyoSure product also competes with alternative therapeutic techniques such as hysteroscopic resection with a monopolar or bipolar loop, which is currently the most common technique for removing intrauterine fibroids and polyps.

Our THS system competes with a number of endoscopy companies including Richard Wolf, Stryker, ACMI/Olympus, and Karl Storz.

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 have historically purchased many of the components and raw materials used in our products from numerous suppliers worldwide. For reasons of quality assurance, scarcity or cost effectiveness, certain components and raw materials used in the manufacture of our products are available only from one or a limited number of suppliers. We have worked closely with our suppliers to develop contingency plans to assure continuity of supply while maintaining high quality and reliability, and in some cases, we have established long-term supply contracts with our suppliers. In certain instances, we have developed in-house capability to offset potential shortages caused by sole source suppliers. Due to the high standards and FDA requirements applicable to the manufacturing of our products, 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 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.

We manufacture our direct radiography detectors at our manufacturing facilities in Newark, Delaware and Warstein, Germany. We manufacture substantially all of our mammography equipment at our manufacturing facilities in Danbury, Connecticut. We recently acquired a small mammography equipment business in Beijing, China. We manufacture our CAD line of products, the SecurView workstations, our osteoporosis screening equipment and our mini C-arm imaging systems at our headquarters in Bedford, Massachusetts. We continue to develop our software for our CAD products at our Santa Clara, California facility. The MammoPad breast cushion is manufactured by third-parties and drop-shipped from our suppliers directly to our customers. Our breast biopsy disposable products are manufactured in Indianapolis, Indiana, as well as in our Costa Rica facility. Our ATEC control consoles for breast biopsy are manufactured by a third-party, with quality control performed by our employees. Our Sentinelle Medical MRI breast coils are manufactured at our Toronto, Canada location. We contract with several third-parties to manufacture certain components of our MammoSite system, and we complete the manufacturing process at our Costa Rica and/or Marlborough locations, depending on the configuration.

Our ThinPrep Processors and ThinPrep Imaging Systems are assembled at our facility in Marlborough, Massachusetts. Our ThinPrep PreservCyt vials are filled at our facility in Londonderry, New Hampshire. Our ThinPrep system filters are manufactured at both our Marlborough and Londonderry facilities. We also have a small facility in Sunnyvale, CA that manufactures our Rapid Fetal Fibronectin products. As a result of our acquisition of Gen-Probe, we also have two manufacturing facilities in San Diego, California, which are used to manufacture certain of our diagnostics products, including our blood screening products. Our blood screening facility meets the strict standards set by CBER for the production of biologic products. In addition, we maintain a manufacturing facility in Manchester, England, which is also used to manufacture certain of our diagnostics products. We also manufacture certain of our molecular diagnostics products at our facility in Madison, Wisconsin.

The manufacture of our NovaSure disposable devices occurs at our facility in Alajuela, Costa Rica. The production of the RF Controller component of our NovaSure system takes place at our Marlborough facility. Our MyoSure products are assembled at our Costa Rica facility.

We continually review our operations and facilities in an effort to reduce costs and increase efficiencies and currently plan to consolidate several of our operations and facilities, including the consolidation of our selenium panel coating production line, currently located in Germany, into our digital detector manufacturing facility in Newark, Delaware, the consolidation of our breast biopsy operations, including manufacturing, research and development and sales support, currently located in Indianapolis, Indiana, into our Costa Rica manufacturing facility and our headquarters facilities in Massachusetts, and the consolidation of our Madison, Wisconsin molecular diagnostics operations into our Gen-Probe facilities in San Diego, California. We may experience unexpected problems and expenses associated with our planned consolidation of operations and facilities that could materially harm our business and prospects.

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We have one third-party manufacturer for each of our molecular diagnostics instrument product lines. KMC Systems, Inc., or KMC Systems, is the only manufacturer of the TIGRIS instrument system; Stratec Biomedical Systems AG, or Stratec, is the only manufacturer of the PANTHER instrument system; and Tecan Group Ltd., or Tecan, is the only manufacturer of the Cervista High Throughput Automation System. We are dependent on these 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.

As noted above, we manufacture our products at a number of different facilities located throughout the world. 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 are subject to the risk of catastrophic loss due to unanticipated events, such as fires, earthquakes, explosions, floods or weather conditions. Our 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 to any of our facilities, which could harm our business and prospects. Because some of our manufacturing operations are located in China, Costa Rica, England and Germany, those manufacturing operations are also subject to additional challenges and risks associated with international operations described below.

Backlog

Our backlog as of November 4, 2012 and November 6, 2011 totaled $284.2 million and $254.6 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. During fiscal 2012, our development projects included the ongoing development, clinical trials and other support for the FDA clearance or approval process for our 3D Dimensions product, as well as the development of improvements to next generation laboratory automation and GYN surgical products. In addition, we have recently initiated development programs to add real-time PCR capabilities for the next-generation PANTHER instrument system and to develop a new, standalone instrument to further automate molecular testing from liquid-based cytology specimens. We anticipate continuing research and development to support these ongoing efforts.

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 $131.0 million, $116.7 million and $104.3 million in fiscal 2012, 2011 and 2010, respectively. These expenses do not include acquired in-process research and development expenses of $4.5 million and $2.0 million in fiscal 2012 and 2010, respectively.

Patents and Proprietary Rights

We rely primarily on a combination of trade secrets, patents, copyrights and confidentiality procedures to protect our technology. Due to the rapid technological changes that characterize the markets we operate in, we believe that the enhancement of existing products, reliance upon trade secrets and unpatented proprietary know-how and the development of new products are generally as important as patent protection in establishing and maintaining a competitive advantage. Nevertheless, we have obtained patents and will continue to make efforts to obtain patents, when available, in connection with our product development program.

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

coming years, certain patents relating to current products will expire in the U.S. and abroad thus allowing third parties to utilize certain of our technologies. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology.

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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 Item 3. Legal Proceedings below and may be notified in the future of claims that we may be infringing intellectual property rights possessed by third-parties. In connection with any such litigation or if any claims are asserted against us or our products, we may seek to enter into settlement and/or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide or be required to litigate such claims. A successful claim by a third-party may require us to remove the accused product from the market or to design around the patented technology, potentially resulting in a less acceptable product.

Regulatory and Reimbursement

Regulatory

The manufacture, sale, lease and service of medical diagnostic and surgical devices intended for commercial use are subject to extensive governmental regulation by the FDA in the United States 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.

The FDA generally must clear the commercial sale of new medical devices. Commercial sales of our medical devices within the United States must be preceded by either a pre-market notification filing pursuant to Section 510(k) of the FD&C Act or the granting of a PMA. A 510(k) pre-market notification filing must contain information establishing that the device to be sold is substantially equivalent to a device commercially distributed prior to May 28, 1976.

The PMA procedure involves a complex and lengthy testing and review process by the FDA and may require several years to obtain. We may need to first obtain an investigational device exemption, known as an IDE, in order to conduct extensive clinical testing of the device to obtain the necessary clinical data for submission to the FDA. The FDA will grant a PMA only if after evaluating clinical data it finds that the safety and effectiveness of the product has been sufficiently demonstrated. This approval may restrict the number of devices distributed or require additional patient follow-up for an indefinite period of time.

Our manufacturing processes and facilities are subject to continuing review by the FDA and foreign governments or their representatives. Adverse findings could result in various actions against us, including withdrawal of approvals and product recall.

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. We believe that the ThinPrep System (including the ThinPrep Imaging System), Rapid Fetal Fibronectin Test, Cervista HPV tests and other affected products operate in a manner that will allow laboratories purchasing these products to comply with CLIA requirements. However, we cannot assure that adverse interpretations of current CLIA regulations or future changes in CLIA regulations would not have an adverse effect on sales of any such products.

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

The FDA requires approval of a biologics license application before a licensed biologic may be legally marketed in the United States. Product approvals may be withdrawn or suspended if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

Certain analyte specific reagents, referred to as ASR products, may be sold without 510(k) clearance or PMA approval. However, ASR products are subject to significant restrictions. The manufacturer may not make clinical or analytical performance claims for the ASR product, may not

promote their use with additional laboratory equipment and may only sell the ASR product to clinical laboratories that are qualified to run high complexity tests under CLIA. Each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory developed test.

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In September 2007, the FDA published guidance for ASRs that define the types of products that can be sold as ASRs. Under the terms of this guidance and the ASR Manufacturer Letter issued in June 2008 by the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA, it may be more challenging for us to market some of our ASR products and we may be required to terminate those ASR product sales, conduct clinical studies and make submissions of the affected products to the FDA for clearance or approval.

Outside the United States, our ability to market our products is contingent upon maintaining our International Standards Organization, or ISO, certification, complying with European directives and in some cases receiving specific marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorizations, pricing and reimbursement vary widely from country to country. Foreign registration is an ongoing process as we register additional products and/or product modifications.

We can give no assurance that the FDA or foreign regulatory agencies will give us requisite approvals, clearances or certifications for any of our product or product enhancements under development on a timely basis, if at all. Moreover, after clearance is given, these agencies can later withdraw the clearance or require us to change the device or its manufacturing process or labeling, to supply additional proof of its safety and effectiveness, or to recall, repair, replace or refund the cost of the medical device, if it is shown to be hazardous or defective. The process of obtaining clearance to market products is costly and time-consuming and can delay the marketing and sale of our products.

In August, 2012, the SEC adopted a new rule requiring disclosures of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by public companies. The new rule will require companies to diligence, disclose and report whether or not such minerals originate from the Democratic Republic of Congo, or DRC, or an adjoining country. If the minerals originated in the DRC, or if a company is not able to establish where the minerals originated, extensive disclosure regarding the sources of the minerals, and in some instances an independent audit of the supply chain, will be required. There may be material costs associated with these disclosure and audit requirements, including compliance costs and costs related to the sourcing and availability of certain minerals used in the manufacture of our products.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including federal and state anti-kickback laws, as well as the U.S. Foreign Corrupt Practices Act, or FCPA. Anti-kickback laws make it illegal for an entity to solicit, offer, receive, or pay remuneration or anything of value in exchange for, or to induce, the referral of business or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any item or service paid for by Medicare, Medicaid or certain other federal and state healthcare programs. The statute has been broadly interpreted to cover a wide array of practices. Some states have passed similar laws and also regulate interactions with health care providers, or HCPs, as well as the requirement to disclose payments to HCPs. The federal government has published regulations that identify safe harbors, which if applicable will assure that certain arrangements will not be found to violate the federal anti-kickback statutes. Similarly, our international operations are subject to the provisions of the FCPA, which prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of influencing any act or decision of such official in his or her official capacity, inducing the official to do any act in violation of his or her lawful duty, or to secure any improper advantage in obtaining or retaining business. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. While we make every effort to comply with applicable law and regulations, 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 may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). If the government were to raise questions about our behavior or find that we have violated these laws, there could be a material adverse effect on our business. Our activities could be subject to challenge for the reasons discussed above, due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010, enacted into law in the U.S. in March 2010, includes 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 hospitals. These reporting provisions preempt state laws that require reporting of the same information, but not those that require reports of different or additional information. We expect compliance with the new healthcare legislation to impose significant additional administrative and financial burdens on us.

Sales of medical devices outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. 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 export of our products to foreign countries.

We are further subject to numerous federal, state and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances, among others. We may be required to incur significant costs to comply with these laws and regulations in the future, and complying with these laws may result in a material adverse effect

upon our business, financial condition and results of operations.

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In August 2010, the FDA issued two reports outlining potential changes to the 510(k) regulatory process. In addition, in January 2011, the FDA issued an implementation plan containing 25 specific actions to be implemented in 2011 relating to the 510(k) regulatory process and associated administrative matters. The FDA also deferred action on several other initiatives, including the creation of a new class of devices that would be subject to heightened review processes, until the Institute of Medicine released a related report on the 510(k) regulatory process in July 2011. The FDA is reviewing the Institute of Medicine s report as well as public input to determine what, if any, recommendations the FDA will adopt with respect to the 510(k) regulatory process. Many of the actions proposed by the FDA could result in significant changes to the 510(k) regulatory process, which would likely complicate the process of obtaining clearance for products by the FDA.

In September 2012, the European Commission proposed new regulations for medical devices. The proposed new regulations cover in one regulation devices that are currently the subject of two separate directives, the Active Implantable Medical Devices Directive and the Medical Devices Directive. The adoption of these regulations may impact our international operations through a broadened scope of medical device oversight and/or regulatory reach. Compliance with the new European Commission regulations, if and when adopted, may impose additional administrative and financial burdens on us.

Federal, state and foreign regulations regarding the manufacture and sale of medical devices and pharmaceuticals are subject to future change. We cannot predict what impact, if any, such changes might have on our business. See Our delay or inability to obtain any necessary United States or foreign regulatory clearances or approvals for our newly developed products and treatments or product enhancements could harm our business and prospects under Item 1A. Risk Factors below.

Reimbursement

In the U.S., the Centers for Medicare & Medicaid Services, known as CMS, establishes policies for the coverage and reimbursement of Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for bone density assessment, endometrial ablations, mammography and other imaging, diagnostic tests and surgical procedures performed using our products. Coverage policies for Medicare patients may vary by regional Medicare carrier in the absence of a national coverage determination and reimbursement rates for procedures will vary based on the geographic price index. Coverage and reimbursement for patients with private insurance is dependent on the individual private payer s decisions and may not follow the policies and rates established by CMS for Medicare. Moreover, private insurance carriers may choose not to follow the CMS reimbursement policies. The use of our products outside the U.S. is similarly affected by reimbursement policies adopted by foreign regulatory authorities and insurance carriers.

Significant reductions in reimbursement rates proposed or implemented for the use of any our products have had and may continue to have a material adverse effect on the sales of those products. On an annual basis, CMS publishes reimbursement rates for laboratory services, physician, hospital and ambulatory surgical center payments. CMS published final 2013 rates on November 1, 2012 The CMS reimbursement rates for 2013 included a general reduction of 27% in the Sustainable Growth Rate, or SGR, factor. This factor is used by CMS in a formula to determine doctor reimbursements and, if implemented, would correspondingly affect the reimbursement for the use of our products. This reduction will go into effect January 1, 2013 unless legislation is passed by Congress.

Currently, there is not an established current procedural terminology, or CPT, code, reimbursement rate or official coverage for the use of 3D mammography (breast tomosynthesis) as it was only approved by the FDA in February 2011 in connection with our PMA application for our Dimensions system. We are working with governmental authorities, professional societies, healthcare providers, insurance companies and other third-party payors in efforts to secure reimbursement for the use of 3D tomosynthesis. However, we can give no assurance that these efforts will be successful. Failure to obtain, or delays in obtaining, adequate reimbursement for the use of 3D mammography would adversely affect sales of our Dimensions 3D systems.

Political, economic and regulatory influences, including those envisioned by the adoption in March 2010 of U.S. healthcare reform, may subject the healthcare industry to fundamental changes. We anticipate that the federal government and certain state legislatures will continue to review and assess alternative healthcare delivery systems and payment methods with the ultimate objective of reducing healthcare costs and expanding access. Healthcare reform proposals and medical cost containment measures in the United States and in many foreign countries could, among other things, limit the use of our products and treatments and further reduce reimbursement available for such use. These reforms or cost containment measures, including the uncertainty in the medical community regarding their nature and effect, could have an adverse effect on our customers purchasing decisions regarding our products and treatments and could harm our business, result of operations, financial condition and prospects.

Employees

As of September 29, 2012, we had approximately 6,157 full-time employees, including 1,850 in manufacturing operations, 857 in research and development, 2,750 in marketing, sales and support services, and 700 in finance and administration. The non-management employees of our Hitec-Imaging subsidiary are represented by a union. Hitec-Imaging s 191 non-management German employees were subject to collective bargaining agreements negotiated on a national and regional basis between Unternehmens-Verband Südôstliches Westfalen e.V., the Employers Association of North Rhine-Westphalia, and the German Metal Workers Union, IndustrieGewerkschaft Metall. In addition, Hitec-Imaging s German employees are represented by a works council, a Betriebsrat, with respect to various shop agreements for social matters and working conditions. We believe that our relationship with our employees is good. Except as described herein, none of our other employees are represented by a union.

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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 less in the second fiscal quarter of the year as compared to other quarters. We expect continuing fluctuations in our manufacture and shipment of blood screening products and instruments to Novartis, which vary each period based on Novartis inventory levels and supply chain needs. Our respiratory infectious disease product line is also subject to significant seasonal and year-over-year fluctuations. In addition, the summer months, which occur during our fiscal fourth quarter, typically have had lower order rates internationally for most of our products.

Item 1A. Risk Factors

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

Risks Relating to our Business

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

Market acceptance of our medical products in the United States and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patients medical expenses by government healthcare programs and third-party payors. The continuing uncertainty surrounding world financial markets and continuing weak worldwide macroeconomic conditions, including as a result of actual or potential debt default by certain European countries, have caused and may continue to cause the purchasers of medical equipment to decrease their medical equipment purchasing and procurement activities. Additionally, constrictions in world credit markets have caused and may continue to cause our customers to experience increased difficulty securing the financing necessary to purchase our products. 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. Furthermore, governments and other third-party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could adversely affect sales of our products. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

Sales and market acceptance of our products is dependent upon the coverage and reimbursement decisions made by third-party payors. The failure of third-party payors to provide appropriate levels of coverage and reimbursement for the use of our products and treatments facilitated by our products could harm our business and prospects.

Sales and market acceptance of our medical products and the treatments facilitated by our products in the United States and other countries is dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. Market acceptance of our products and treatments has and will continue to depend upon our customers ability to obtain an appropriate level of coverage for, and reimbursement from third-party payors for, these products and treatments. In the U.S., CMS establishes coverage and reimbursement policies for healthcare providers treating Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for our products and treatments. Coverage policies for Medicare patients may vary by regional Medicare carriers in the absence of a national coverage determination and reimbursement rates for treatments may vary based on the geographic price index. Coverage and reimbursement policies and rates applicable to patients with private insurance are dependent upon individual private payor decisions which may not follow the policies and rates established by CMS. The use of our products and treatments outside the United States is similarly affected by coverage and reimbursement policies adopted by foreign governments and private insurance carriers.

Significant reductions in reimbursement rates proposed or implemented for the use of any our products have had and may continue to have a material adverse effect on the sales of those products. On an annual basis, CMS publishes reimbursement rates for laboratory services, physician, hospital and ambulatory surgical center payments. CMS published final 2013 rates on November 1, 2012 The CMS reimbursement rates for 2013 included a general reduction of 27% in the SGR factor. This factor is used by CMS in a formula to determine doctor reimbursements and, if implemented, would correspondingly affect the reimbursement for the use of our products. This reduction will go into effect in January 1,

2013 unless legislation is passed by Congress.

Currently, there is not an established CPT code, reimbursement rate or official coverage for the use of 3D mammography (breast tomosynthesis) as it was only approved by the FDA in February 2011 in connection with our PMA application for our

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Dimensions system. We are working with governmental authorities, professional societies, healthcare providers, insurance companies and other third-party payors in efforts to secure reimbursement for the use of 3D mammography. However, we can give no assurance that these efforts will be successful. Failure to obtain, or delays in obtaining, adequate reimbursement for the use of 3D tomosynthesis would adversely affect sales of our Dimensions 3D systems.

The adoption of healthcare reform in the United States and the uncertainty surrounding the implementation of these reforms could harm our business and prospects.

The healthcare industry has undergone significant change driven by various efforts to reduce costs, trends toward managed care, cuts in Medicare, consolidation of healthcare distribution companies and collective purchasing arrangements by office-based healthcare practitioners. The effect of the implementation of the Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010, enacted into law in the U.S. in March 2010, on our business is uncertain. Among other things, the law requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on U.S. sales of certain medical devices beginning January 1, 2013. We expect that this excise tax will apply to the majority, if not all, of our products sold in the U.S. U.S. net product sales represent, and will likely continue to represent a substantial majority of our net revenues. Our U.S. product sales represented 73% and 76% of our net product sales for the years ended September 29, 2012 and September 24, 2011, respectively. The law also includes new regulatory mandates and other measures designed to constrain medical costs, as well as stringent new reporting requirements of financial relationships between device manufactures and physicians and hospitals. We expect compliance with the new healthcare legislation, including with these new reporting requirements and the new excise tax, to impose significant additional administrative and financial burdens on us. Various healthcare reform proposals have also emerged at the state level. The healthcare reform legislation and these proposals could reduce medical procedure volumes and impact the demand for our products or the prices at which we sell our products. In addition, the excise tax will increase our costs of doing business. The impact of this healthcare reform legislation and these proposals could harm our business and prospects, results of operations and/or financial condition. Healthcare reform proposals and medical cost containment measures in the United States 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, result of operations, financial condition and prospects.

Changes in laws affecting the healthcare industry 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 health care availability, method of delivery and payment for health care 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 our 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 can 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 by ACOG in November 2009 and guidelines released in March 2012 by the U.S. Preventative Services Task Force, known as the USPSTF, and the American Cancer Society.

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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.

We are devoting significant resources to our continuing research and development programs which are designed to develop new products and treatments and to enhance and improve our existing products and treatments. The successful development of our products and product enhancements is subject to numerous risks, both known and unknown, including:

- unanticipated delays in development, clinical trials or the approval or clearance process by the FDA or other applicable regulatory authority;
- access to capital;
- budget overruns;
- third-party intellectual property;
- technical problems; and
- other difficulties that could result in the abandonment or substantial change in the design, development and commercialization of these new products, including, for example, changes requested by the FDA in connection with pre-market approval applications for products or 510(k) clearance.

Given the uncertainties inherent with product development, introduction, and enhancement our efforts may not be completed on a timely basis or within budget, if at all. Our failure to develop new products and product enhancements on a timely basis or within budget, if at all, could harm our business and prospects.

If we cannot maintain our current corporate collaborations and enter into new corporate collaborations, our product development could be delayed. In particular, any failure by us to maintain our blood screening collaboration with Novartis could have a material adverse effect on our business.

Gen-Probe has relied, to a significant extent, on corporate collaborators for funding the development of and marketing for certain of its products. In addition, we expect to rely on our corporate collaborators for the commercialization of certain products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. We cannot control the amount and timing of resources our corporate collaborators devote to our programs or potential products.

The continuation of any of these collaboration agreements depends upon their periodic renewal by us and our collaborators. For example, in January 2009 Gen-Probe extended the term of its blood screening collaboration with Novartis to June 30, 2025, subject to earlier termination under certain limited circumstances specified in the collaboration agreement. The collaboration was previously scheduled to expire by its terms in 2013.

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. We may not be able to negotiate additional corporate collaborations on acceptable terms, if at all, and these collaborations may not be successful. In addition, in the event of a dispute under our current or any future collaboration agreements, such as our agreements with Novartis, 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.

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

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

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

Blood screening and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States 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 FDA requirements relating to the Quality System Regulation. 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.

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

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

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

The FDA and similar governmental bodies in other countries have the authority to require the recall of medical products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall could harm the reputation of our products and adversely affect our business and prospects. In the past, Gen-Probe voluntarily recalled products, which, in each case, required it to identify a problem and correct it. In May 2011, Gen-Probe voluntarily recalled certain Elucigene test kits for the detection of genetic mutations associated with cystic fibrosis because of issues Gen-Probe identified during quality control stability testing. All affected customers and appropriate regulatory authorities were advised of the voluntary recall and Gen-Probe made a substitute product available. The affected product is CE marked, but is not cleared by the FDA and is not available for sale in the United States. In addition, in May 2011 Gen-Probe initiated a second voluntary recall of certain Elucigene branded tests in Canada upon determination that such products were not properly registered with Health Canada. In April 2012, Gen-Probe voluntarily recalled certain lots of LIFECODES PAK (platelet antibody) products after determining that the negative controls in the assays were increasing signals over time, leading to the potential for decreased product performance.

Our products may be subject to a future government-mandated recall or further voluntary recalls, and any such recalls could divert managerial and financial resources, be more difficult and costly to correct, result in the suspension of sales of certain of our products and/or harm our reputation and financial results.

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

We and our contract manufacturers manufacture our products at a relatively limited number of different facilities located throughout the world. 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 are subject to the risk of catastrophic loss due to unanticipated events, such as fires, earthquakes, explosions, floods or weather conditions. Our 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 to any of our facilities, which could harm our business and prospects. Because some of our manufacturing operations are located outside the United States, including in Germany, Canada, Costa Rica, the United Kingdom and China, those manufacturing operations are also subject to additional challenges and risks associated with international operations described below.

Our delay or inability to obtain any necessary United States 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 delay or inability to obtain any necessary United States 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.

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Medical devices cannot be marketed in the United States 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 United States must also be manufactured in compliance with FDA Good Manufacturing Practices, which regulate the design, manufacture, packing, storage and installation of medical devices. Moreover, medical devices are required to comply with FDA regulations relating to investigational research and labeling. States may also regulate the manufacture, sale and use of medical devices, particularly those that employ x-ray technology. Our products are also subject to approval and regulation by foreign regulatory and safety agencies.

Delays in receipt of, or failure to obtain, clearances or approvals for future products could delay or preclude realization of product revenues from new products or result in substantial additional costs which could decrease our profitability. In August 2010, the FDA issued two reports outlining potential changes to the 510(k) regulatory process. In addition, in January 2011, the FDA issued an implementation plan containing 25 specific actions to be implemented in 2011 relating to the 510(k) regulatory process and associated administrative matters. The FDA also deferred action on several other initiatives, including the creation of a new class of devices that would be subject to heightened review processes, until the Institute of Medicine released a related report on the 510(k) regulatory process in July 2011. The FDA is reviewing the Institute of Medicine s report as well as public input to determine what, if any, recommendations the FDA will adopt with respect to the 510(k) regulatory process. Many of the actions proposed by the FDA could result in significant changes to the 510(k) regulatory process, which would likely complicate the process of obtaining clearance for products by the FDA. In September 2012, the European Commission proposed new regulations for medical devices. The proposed new regulations cover in one regulation devices that are currently the subject of two separate directives, the Active Implantable Medical Devices Directive and the Medical Devices Directive. The adoption of these regulations may impact our international operations through a broadened scope of medical device oversight and/or regulatory reach. Compliance with the new European Commission regulations, if and when adopted, may impose additional administrative and financial burdens on us.

The 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 perceptions 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.

The markets for our Dimensions 3D tomosynthesis system may not develop as expected.

The markets for our Dimensions 3D tomosynthesis system and related products may not continue to develop as expected. There is a significant installed base of conventional digital and screen-film mammography products in hospitals and radiological practices. The use of our Dimensions 3D tomosynthesis system in many cases would require these potential customers to either modify or replace their existing x-ray imaging equipment. As our Dimensions 3D tomosynthesis systems are generally more

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expensive than conventional mammography products, we believe that a major factor in the market s acceptance of Dimensions 3D tomosynthesis systems has been and will continue to be based upon the benefits of tomosynthesis as compared to less expensive technologies. Moreover, as a new technology, there is currently limited, if any, reimbursement for the use of 3D tomosynthesis. We believe that our ability to continue to gain market acceptance of the Dimensions 3D tomosynthesis system and follow-on products depends on our ability to demonstrate the clinical efficacy and cost-effectiveness of the Dimensions 3D tomosynthesis system and to secure reimbursement to support the use of 3D tomosynthesis. We are seeking to work with healthcare providers, insurance companies and other third-party payors in connection with our efforts to promote, and to secure reimbursement for, the use of 3D tomosynthesis. However, we can give no assurance that these efforts will be successful. The markets for our Dimensions 3D tomosynthesis system and related products have and will continue to be affected by published studies and reports relating to the comparative efficacy of tomosynthesis, as well as decisions relating to the reimbursement of healthcare providers for the use of the system. The publication of an adverse study, or an adverse decision relating to the reimbursement of the use of tomosynthesis, would likely significantly impair the adoption of this technology and harm our business. Sales of our Dimensions 3D tomosynthesis system may also be adversely affected by increased competition. Several companies, including Siemens, Giotto, Philips and Planmed, have recently introduced 3D tomosynthesis systems in certain foreign countries. We also are aware that other companies, several of which have substantially greater resources than we have, such as GE and Siemens, are developing 3D tomosynthesis systems for approval in the U.S. Because the markets for our Dimensions 3D tomosynthesis system and related products are relatively new, it is likely that our evaluation of the potential markets for these products will materially vary with time.

Our business may be harmed by the acquisition of Gen-Probe, our other prior acquisitions or acquisitions we may complete in the future.

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

problems may arise with our ability to successfully integrate the acquired businesses, which may result in us not operating as effectively and efficiently as expected, and may include:

diversion of management time, as well as a shift of focus from operating the businesses to issues related to integration and administration or inadequate management resources available for integration activity and oversight;

failure to retain and motivate key employees;

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

failure to successfully obtain appropriate regulatory approval or clearance for products under development;

failure to successfully manage relationships with customers, distributors and suppliers;

failure of customers to accept new products;

failure to effectively coordinate sales and marketing efforts;

failure to combine product offerings and product lines quickly and effectively;

failure to effectively enhance acquired technology and products or develop new products relating to the acquired businesses;

potential difficulties and inefficiencies in managing and operating businesses in multiple locations or operating businesses in which we have either limited or no direct experience;

potential difficulties integrating financial reporting systems;

potential difficulties in the timely filing of required reports with the SEC; and

potential difficulties in implementing controls, procedures and policies, including disclosure controls and procedures and internal controls over financial reporting, appropriate for a larger public company at companies that, prior to the acquisition of such companies, had lacked such controls, procedures and policies, which may result in ineffective disclosure controls and procedures or material weaknesses in internal controls over financial reporting;

we may not be able to achieve the expected synergies from an acquisition or it may take longer than expected to achieve those synergies;

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- an acquisition may result in future impairment charges related to a decline in the fair value of the acquired business as compared to the price we paid for such acquisition;

- an acquisition may involve restructuring operations or reductions in workforce which may result in substantial charges to our operations;

- our current and prospective customers and suppliers may experience uncertainty associated with an acquisition, including with respect to current or future business relationships with us and may attempt to negotiate changes in existing business;

- an acquisition may involve unexpected costs or liabilities, including as a result of pending and future shareholder lawsuits relating to acquisitions or exercise by shareholders of their statutory appraisal rights, or the effects of purchase accounting may be different from our expectations;

- an acquisition may involve significant deferred or contingent payments that may adversely affect our future liquidity or capital resources; and

- the acquired businesses may be adversely affected by future legislative, regulatory, or tax decisions and/or changes as well as other economic, business and/or competitive factors.

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

If we are successful in pursuing future acquisitions, we may be required to expend significant funds, incur additional debt or other obligations, or issue additional securities, which may negatively affect our operating results and financial condition. If we spend significant funds or incur additional debt or other obligations, our ability to obtain financing for working capital or other purposes could decline, and we may be more vulnerable to economic downturns and competitive pressures. We cannot guarantee that we will be able to finance additional acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

We will incur significant acquisition-related costs in connection with the acquisition of Gen-Probe.

We have incurred and expect to incur additional significant costs associated with our acquisition of Gen-Probe and combining the operations of the two companies. The substantial majority of the expenses resulting from the acquisition were comprised of transaction costs related to investment banker fees and other professional services as well as systems consolidation costs and business integration and employment-related costs, including costs for severance, retention and other restructuring activities. Additional unanticipated costs may be incurred in the integration of the two companies businesses. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, should allow us to offset incremental transaction and acquisition-related costs over time, this net benefit may not be achieved in the near term, or at all.

Our business may be harmed by the contingent earn out obligations we incurred in connection with our acquisitions or acquisitions we may complete in the future.

In connection with certain of our acquisitions, we have incurred the obligation to make contingent earn out payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period. We also expect that acquisitions we may complete in the future may contain contingent earn out payments, and these payments could be significant. In certain circumstances, such as a change of control, a portion of these obligations may be accelerated. In addition, contractual provisions relating to these contingent earn out obligations may include covenants to operate the acquired businesses in a manner that may not otherwise be most advantageous to us. These provisions may also result in the risk of litigation relating to the calculation of the amount due or our operation of the acquired business. Such litigation could be expensive and divert management attention and resources. Our obligation to make contingent payments may also result in significant operating expenses. Depending upon the particular facts and circumstances giving rise to the payment and our previous estimates, all or a portion of these payments may be required to be expensed by us when accrued. For example, our contingent earn out obligations payable in connection with the TCT and Healthcome acquisitions will be fully expensed as accrued because our obligation to make these payments is conditioned on the continued employment of certain key employees of TCT and Healthcome. We can give no assurance that we will have sufficient funds to pay

our contingent obligations when due, or that such obligations, including the associated covenants relating to the operation of the acquired business, will not otherwise adversely affect our business, liquidity, capital resources or results of operations.

It may be difficult for us to implement our strategies for improving growth.

Some of the markets in which we compete have been flat or declining over the past several years. To address this issue, we are pursuing a number of strategies to improve our growth, including:

- expanding our product offerings;
- allocating research and development funding to products with higher growth prospects;
- developing new applications for our technologies;

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- strengthening our presence in selected geographic markets;
- acquiring technologies and businesses that complement or augment our existing products and services;
- implementing targeted customer initiatives; and
- supporting cross-selling opportunities of products and services to take advantage of the breadth of our product offerings.

We may not be able to successfully implement these strategies, and these strategies may not result in the growth of our business.

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 hospitals and clinical laboratories. This consolidation has resulted in greater pricing pressures, decreased average selling prices, and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may reduce competition and continue to exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations. In particular, we are dependent upon a relatively small number of large clinical laboratory customers in the United States 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 United States 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.

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. In addition, we have acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure, Inc. 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.

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, and copyrights to protect our products and technology. Despite these precautions, unauthorized third parties may infringe our intellectual property, or copy or reverse engineer portions of our technology. The pursuit

and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. We do not know if current or future patent applications will be issued with the full scope of the claims sought, if at all, or whether any patents that do issue will be challenged or invalidated. The patents that we own or license could also be subject to interference proceedings or similar disputes over the priority of the inventions, and an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to the technology from the prevailing party. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us.

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We have obtained or applied for corresponding patents and patent applications in several foreign countries for some of our 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.

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 technology that our patents do not cover. In addition, because patent applications in the United States 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. 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.

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.

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

We are subject to a number of additional risks and expenses due to our international operations, including our operations in China. Any of these risks or expenses could harm our operating results. These risks and expenses include:

- difficulties in staffing and managing operations in multiple locations as a result of, among other things, distance, language and cultural differences;
- protectionist laws and business practices that favor local companies;
- difficulties in the collection of trade accounts receivable;
- difficulties and expenses related to implementing internal controls over financial reporting and disclosure controls and procedures;
- expenses associated with customizing products for clients in foreign countries;
- possible adverse tax consequences;

the inability to obtain favorable third-party reimbursements;