HOLOGIC INC
Form 10-K
November 23, 2011
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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 24, 2011

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 Incorporation or Organization)	(IRS Employer 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 26, 2011 was $5,674,600,267 based on the price of the last reported sale on the Nasdaq Global Select Market on that date.

As of November 16, 2011, there were 263,116,399 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 24, 2011 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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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, including the excise tax on the sale of most medical devices, on our business and results of operation;
- the impact and anticipated benefits of recently completed acquisitions and acquisitions we may complete in the future;
- 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;
- compliance with covenants contained in our long-term leases;

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 those discussed in the Risk Factors set forth in Part I Item 1A below as well as those discussed elsewhere in this report. We qualify all of our forward-looking statements by these cautionary statements.

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PART I

Item 1. Business

Overview

We are a developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to the healthcare needs of women. Our core business segments are focused on Breast Health, Diagnostics, GYN Surgical and Skeletal Health.

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 (MRI) breast coils, computer-aided detection (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. We have also developed a new breast imaging platform, Dimensions, which utilizes a new technology, tomosynthesis, to produce three dimensional (3D) images, as well as conventional two dimensional (2D) full field digital mammography images. In the U.S., our Dimensions product had previously been approved by the Food and Drug Administration (FDA) for providing conventional 2D images. On February 11, 2011, we received approval from the FDA to enable the 3D tomosynthesis capability of our Dimensions system. The FDA granted approval for the use of 3D tomosynthesis in addition to a conventional 2D digital image. 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. We began to sell our Dimensions 3D tomosynthesis system in the United States immediately following FDA approval. We had been selling Dimensions 3D tomosynthesis outside of the United States in regions such as Canada, Europe, Latin America and Asia.

In July 2011, we completed our acquisition of Beijing Healthcome Technology Company, Ltd. (Healthcome), a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China. Healthcome develops and manufactures analog mammography products targeted to lower tier hospital segments in China.

Our Diagnostics products include the ThinPrep System, which is primarily used in cytology applications such as cervical cancer screening, the Rapid Fetal Fibronectin Test, which assists physicians in assessing the risk of pre-term birth, and our molecular diagnostic reagents used for a variety of DNA and RNA analysis applications based on our proprietary Invader chemistry. Our current molecular diagnostic offerings based upon this Invader chemistry include Cervista HPV high risk (HR) and Cervista HPV 16/18 products to assist in the diagnosis of human papillomavirus (HPV), as well as other products to diagnose cystic fibrosis, cardiovascular risk and other diseases.

In June 2011, we acquired TCT International Co., Ltd. (TCT) and subsidiaries, a privately-held distributor of medical products, including our ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT s operating subsidiaries are located in Beijing, China. Our acquisition of TCT provides us with an established nationwide sales organization and customer support infrastructure in China. TCT is primarily reported within our Diagnostics segment and to a lesser extent within our GYN Surgical segment.

Our GYN Surgical products include the NovaSure Endometrial Ablation System, the MyoSure Hysteroscopic Tissue Removal System, and the Adiana Permanent Contraception System. The NovaSure system is a minimally invasive procedure for the treatment of heavy menstrual bleeding. The MyoSure system is a tissue removal device that is designed to provide incision-less removal of fibroids and polyps within the uterus. The MyoSure system was added to the GYN Surgical product portfolio as a result of our acquisition of Interlace Medical, Inc. (Interlace) on January 6, 2011. The Adiana system is a form of permanent female contraception intended as an alternative to tubal ligation.

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

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, ATEC, Celero, Cervista, Dimensions, Eviva, Fluoroscan, Invader, LORAD, MammoPad, MammoSite, MultiCare, MyoSure, NovaSure, PreservCyt, QDR, Rapid fFN, Sahara, SecurView, Selenia, Sentinelle, Suresound, StereoLoc, ThinPrep, THS, TCT, TLI IQ, and Trident.

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 (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 13 to our consolidated financial statements contained in Item 15 of this Annual Report.

Breast Health Products

Our breast health products include a broad portfolio of breast imaging and related products and accessories, including digital and film-based mammography systems, MRI breast coils, 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. We have also developed a new breast imaging platform, Dimensions, which utilizes a new technology, tomosynthesis, to produce 3D images.

Selenia Full Field Digital Mammography System

The Selenia full field digital mammography system is based on our proprietary DirectRay digital detector, which preserves image quality by using a compound known as amorphous selenium to directly convert x-rays to electronic signals. Many other digital technologies employ an indirect two-step process by first converting x-ray

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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. Our DirectRay flat panel detector technology 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.

The Selenia product family has a number of other 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 (PACS) and Radiology Information Systems (RIS). The Selenia product family includes the Selenia base configuration, the Selenia S configuration (a screening-only configuration), the Selenia Value (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.

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. On February 11, 2011, we received approval from the FDA to enable the 3D tomosynthesis capability of our Dimensions system. The FDA granted approval for the use of 3D tomosynthesis in addition to a conventional 2D digital image. 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.

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 DirectRay digital detector with the Healthcome mammography platform. This new digital product is being locally designed and sourced to meet the performance and pricing requirements of the mid-tier hospital market segment. This new digital product will require local regulatory approval. We submitted the regulatory package requesting this approval in fiscal 2011; however, we cannot assure that we can complete the development of this new product on a timely basis if at all, or if developed, it will be commercially successful.

Screen-Film Mammography Systems

Our screen-film mammography systems include our LORAD M-IV and M-IV Platinum systems. 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.

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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 increasing cancer detection. We have integrated our mammography applications CAD software tools into our line of multi-modality breast imaging workstations. 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.

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 product, the ATEC (Automated Tissue Excision Collection) 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, 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 (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. We introduced our multi-lumen device, the MammoSite ML radiation therapy system, in the fourth quarter of 2009. 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.

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Photoconductor Coatings

Our AEG Elektrofotografie GmbH (AEG) subsidiary is our sole supplier of the amorphous selenium photoconductor coatings employed in our Selenia and Dimensions full-field digital mammography detectors. AEG 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. During the fourth quarter of fiscal 2009, we closed our organic photoconductor drum coatings manufacturing operations in Shanghai, China, and completed the sale of the capital stock of this operation in the second quarter of fiscal 2010.

Sentinelle Medical MRI Coils and Workstation

Our Sentinelle Medical subsidiary develops, manufactures and sells 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 MR imaging 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

On August 19, 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 a breast biopsy procedure. Trident incorporates our amorphous selenium based detector technology. It is a compact and portable unit designed to be used in the same room where breast biopsy procedure has taken place. This is different from traditional x-ray verification systems, which are larger and generally located outside of the examination room. Performing verification in the same room as the procedure or nearby can improve workflow and reduce the time the patient needs to be under examination. Commercialization of this product commenced in the first quarter of fiscal 2012.

Diagnostic Products

Our diagnostic product offerings include the ThinPrep System used primarily for cytology applications, such as cervical cancer screening, and the Rapid Fetal Fibronectin Test for pre-term birth risk assessment. Our molecular diagnostic reagents are used for DNA and RNA analysis applications based on our proprietary Invader chemistry, including our two HPV tests approved by the FDA in 2009.

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.

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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. Non-gynecological cytology applications include fine-needle aspiration specimens (e.g., breast, thyroid, lung or liver), body fluids (e.g., urine, pleural fluid, ascitic fluid, pericardial fluid), respiratory specimens (e.g., sputum, brushing of respiratory tracts) and ancillary testing (e.g., cell blocks, immunocytochemistry, special stains).

Rapid Fetal Fibronectin Test

The Rapid Fetal Fibronectin Test is a patented single-use disposable test used to determine a woman s risk of 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.

HPV Offering and InVitro Diagnostics

Invader Chemistry. 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.

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: 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. The Cervista HPV HR test is an in vitro diagnostic test for the qualitative detection of DNA from the fourteen high-risk HPV types responsible for most cervical disease. The Cervista HPV 16/18 test is an in vitro diagnostic test for the qualitative detection of DNA from HPV types 16 and 18, the types that cause approximately 70% of cervical cancer. We received FDA approval for these two tests in March 2009.

Cervista HPV HR has been approved for triaging women with undetermined cervical cytology and co-testing with cervical cytology for women 30 years and older. Our Cervista HPV 16/18 has been approved to be used adjunctively with Cervista HPV HR 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 HR test.

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We are currently developing a high throughput instrumentation solution for Cervista testing. The instrument in development automates all steps in the Cervista HR in the testing process. Commercialization of this instrumentation is subject to FDA approval. We submitted the approval package to the FDA for the automated product in April 2011. We cannot assure that we will obtain FDA approval of this automated product on a timely basis, if at all, or that if approved it will be commercially successful.

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

A molecular assay is cleared for use 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 the Invader Chemistry.

GYN Surgical Products

Our surgical product offerings include the NovaSure system, the MyoSure system, the Adiana system, and the THS system.

NovaSure

The NovaSure system is 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 safe, efficient, 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. The MyoSure procedure requires a source of visualization, a fluid delivery system and a regulated vacuum source, each of which is not included with the MyoSure system.

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Adiana

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. Patients are often able to return to work or resume their daily activities within one day. In contrast, tubal ligation, a traditional method of female permanent contraception, requires more invasive surgical procedures, is usually conducted in a hospital under general anesthesia and typically requires several days of recovery.

During the Adiana procedure, a slender, flexible instrument is passed through the body s natural openings to deliver a low level of RF energy to a small section of each fallopian tube. A tiny, soft insert, about the size of a grain of rice, is then placed in each fallopian tube in the location where the energy was applied. During the three months following the procedure, the patient continues to use temporary birth control while new tissue grows in and around the Adiana inserts, eventually blocking the fallopian tubes. At three months, a special x-ray test (called a hysterosalpingogram or HSG) is performed to confirm the fallopian tubes are completely blocked and the patient may begin relying on the Adiana System for permanent contraception. Because the Adiana insert is fully contained within the fallopian tube and does not use metal, the procedure leaves nothing in the uterus that could interfere with future intra-uterine procedures such as endometrial ablation.

In connection with Conceptus, Inc. s ongoing patent litigation against us in the United States District Court for the Northern District of California, on October 17, 2011 the jury returned a verdict in favor of Conceptus, finding that the Adiana system infringes two claims of a single Conceptus patent and awarded damages to Conceptus. Post trial motions will be filed addressing certain issues that could impact the ultimate outcome of the case. We also expect that Conceptus will seek to enjoin us from further sales of the Adiana system. A hearing on the post trial motions and injunction request is scheduled for December 22, 2011. The jury verdict and any such determinations are subject to appeal by either party. If Conceptus is successful in upholding the verdict, we may be required to remove the Adiana system from the market.

Towerfree Hysteroscopy System

The Towerfree Hysteroscopy System (THS) is a hysteroscope 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 intraurine 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 allow optimal procedural conditions for the physician as well as enhance 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.

Skeletal Health Products

Our skeletal health products include a family of QDR dual energy x-ray bone densitometers and the Sahara Clinical Bone Sonometer and our mini C-arm imaging 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

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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.

Recent Acquisitions

Our goal to provide a broad range of best-in-class products for screening, diagnosis and treatment to help women lead longer, healthier lives requires a wide variety of technologies, products and capabilities. To achieve this goal, in addition to internally developed growth through research and development efforts, we have obtained products and the necessary specialized expertise in different areas through acquisitions. In furtherance of this goal, during fiscal 2011 we acquired the following businesses:

- In January 2011, we acquired Interlace, a privately-held developer, manufacturer, and supplier of the MyoSure system located in Framingham, Massachusetts.

- In June 2011, we acquired TCT and subsidiaries, a privately-held distributor of medical products, including our ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT s operating subsidiaries are located in Beijing, China.

- In July 2011, we acquired Healthcome, a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China.

Additional information pertaining to our acquisitions is contained in Note 3 to our consolidated financial statements contained in Item 15 of this Annual Report and Management s Discussion and Analysis of Financial Condition and Results of Operations Acquisitions contained in Item 7 of this Annual Report.

We expect to continue to make future investments or acquisitions to further strengthen our existing businesses, including our presence in selected geographic markets. Mergers and acquisitions of medical technology companies and companies in diverse geographical locations are inherently risky and we cannot assure that any of our previous or future acquisitions will be successful or will not otherwise have a material adverse impact on our results of operations, financial condition or cash flows.

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 2011, 2010 and 2009, no customer accounted for more than 10% of our consolidated revenues. In fiscal 2011, 2010 and 2009, foreign sales accounted for approximately 24%, 21% and 20% of our product sales, respectively. See Note 13 to our consolidated financial statements contained in Item 15 of this Annual Report for geographical information concerning those sales.

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As of September 24, 2011, our direct sales and service force consisted of approximately 2,089 people.

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 (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 (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 product.

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 Diagnostic sales specialist 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.

As of September 24, 2011, we employed approximately 648 people as field service engineers, internal technical support personnel and related administrative personnel.

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Competition

The healthcare industry is highly competitive and characterized by continual change and improvements in technology. The 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, 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 cannot assure that we will be able to compete successfully with existing or new competitors.

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 to customers. This includes, but is not limited to, superiority in efficacy, ease of use, reliability, 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 (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, Philips and Planmed. We also understand that GE is developing a 3D tomosynthesis system. Although 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 the Company s Dimensions system, that have been so approved by the FDA. Any such use will require pre-market approval (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 those sold by Invivo, 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 certain 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.

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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 are currently the only provider of a molecular test for predicting the risk of preterm birth in the United States, and internationally, our 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 preterm 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 clinical market, we compete with several companies offering alternative technologies to the Invader chemistry including Abbott Laboratories, Siemens, Becton, Dickinson and Company, Qiagen, Roche Diagnostics Corporation, Gen-Probe, Applera Corporation, Applied Biosystems, Celera, Innogenetics, Inc., and Luminex Corporation. Our Cervista HPV HR test, which was approved by the FDA in March 2009, competes with tests marketed by Qiagen, which received FDA approval in 1999, Roche Diagnostics, which received PMA approval for a high risk HPV test and 16/18 test in 2011, and Gen-Probe, which received PMA approval for a high risk HPV test in 2011.

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, there exist 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 & 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 and 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 Adiana product competes directly with Conceptus, Inc. s Essure product, marketed for hysteroscopic sterilization. In addition, the Adiana system competes with traditional permanent contraception methods, such as tubal ligation and vasectomy, as well as with other products used for temporary birth control methods, such as diaphragms, condoms, spermicides, birth control pills and IUDs.

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 have faced competition from Orthoscan in the mini-C arm market.

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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, sole source availability or cost effectiveness, certain components and raw materials used in the manufacture of our products are available only from one supplier. 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 and certain of our breast biopsy systems at our manufacturing facilities in Danbury, Connecticut. We manufacture our CAD line of products, the SecurView Work Stations, our osteoporosis assessment 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. 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.

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. 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. 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. We manufacture our Adiana system at our manufacturing facility in Costa Rica, although the Adiana RF Controller, SureSound and the THS are supplied through third-parties. Our MyoSure products are assembled at both our Framingham, Massachusetts, and Marlborough facilities. We are in the process of fully transitioning production of this product from Framingham to Marlborough.

We manufacture our molecular diagnostics products at our facility in Madison, Wisconsin and source certain components from various contract manufacturers.

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 Germany, Costa Rica and China, those manufacturing operations are also subject to additional challenges and risks associated with international operations described below.

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Backlog

Our backlog as of November 6, 2011 and November 7, 2010 totaled $254.6 million and $274.4 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 2011, 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. 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 (CE marking). Our research and development expenses were $116.7 million, $104.3 million and $102.5 million in fiscal 2011, 2010 and 2009, respectively. These expenses do not include acquired in-process research and development expenses of $2.0 million in fiscal 2010.

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 improvement 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 be issued with the 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 be granted or that granted patents will not provide significant protection for our products and technology. Unauthorized third parties may infringe our intellectual property rights, 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.

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.

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We are engaged in intellectual property litigation as described in Item 3, Legal Proceedings, 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. In connection with Conceptus, Inc. s ongoing patent litigation against us in the United States District Court for the Northern District of California, on October 17, 2011 the jury returned a verdict in favor of Conceptus, finding that the Adiana system infringes two claims of a single Conceptus patent and awarded damages to Conceptus. Post trial motions will be filed addressing certain issues that could impact the ultimate outcome of the case. We also expect that Conceptus will seek to enjoin us from further sales of the Adiana system. A hearing on the post trial motions and injunction request is scheduled for December 22, 2011. The jury verdict and any such determinations are subject to appeal by either party. If Conceptus is successful in upholding the verdict, we may be required to remove the Adiana system from the market. Any 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 other claims for indemnification by customers resulting from infringement claims, whether or not proven to be true, may harm our business and prospects.

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.

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. Moreover, some of our technology is governed by the International Traffic in Arms Regulations of the United States Department of State. As a result, the export of some of our systems to some countries may be limited or prohibited.

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.

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The laboratories that purchase our ThinPrep System, ThinPrep Imaging System, Rapid Fetal Fibronectin Test and Cervista HPV tests are subject to extensive regulation under the Clinical Laboratory Improvement Amendments of 1988 (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 and Cervista HPV tests 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 the ThinPrep System, ThinPrep Imaging System, the Rapid Fetal Fibronectin Test, and the Cervista HPV tests.

The majority of the molecular diagnostic products we acquired as part of the Third Wave acquisition were sold as Analyte Specific Reagents, known as ASRs. The FDA restricts the sale of these products to clinical laboratories certified under CLIA to perform high complexity testing and also restricts the types of products that can be sold as ASRs. In 2006, followed by additional clarification in 2007, the FDA issued guidance concerning acceptable examples of reagents that meet the threshold of the ASR regulations. In this guidance, the FDA outlined examples of products and marketing practices that go beyond the scope of the ASR regulations making the reagent part of a test system potentially subject to premarket review. These examples include combining, or promoting for use, a single ASR with another product such as other ASRs, general purpose reagents, controls, laboratory equipment, software, etc., or promoting an ASR with specific analytical or performance claims, instructions for use in a particular test, or instructions for validation of a specific test using the ASR. As a result of this guidance we took appropriate steps to discontinue certain Third Wave products that were previously sold as ASRs. We received investigational device exemptions for the remaining products allowing us the ability to continue commercialization while we obtain FDA clearance through the 510(k) process.

We cannot assure that the FDA or foreign regulatory agencies will give the requisite approvals or clearances for any of our medical devices 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.

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 (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 the interactions with Health Care Providers (HCP) 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

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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.

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.

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.

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 Decision 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 and insurance carriers.

In November 2011, CMS announced 2012 reimbursement rates for physician, hospital and ambulatory surgical center payments. For 2011, as part of US healthcare reform legislation, which was passed on March 23, 2010, reimbursement for bone density screening in 2010 and 2011 was adjusted to 70% of the 2006 rates. This resulted in an approximate increase of 60% of the rates published in the 2010 CMS Physician Fee Schedule. However, unless future legislation is adopted, the reimbursement for bone density screening will revert in 2012 to the prior CMS Physician Fee Schedule, which would result in an over 40% reduction in reimbursement for such screening, as compared to 2011 reimbursement rates. The CMS reimbursement rates for 2012 also include a general reduction of 27% in the Sustainable Growth Rate (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. Congress has, from time to time, overridden some or all of the proposed reductions in reimbursement. However, we cannot assure that Congress will override any part of the recent proposed reductions. Significant reductions in reimbursement rates proposed or implemented for the use of any our products has had and may continue to have a material adverse affect on the sales of those products.

CMS has not adopted a reimbursement rate for the use of 3D tomosynthesis, as tomosynthesis was only recently approved by the FDA in February 2011 in connection with our PMA application for our Dimensions system. We are working with governmental authorities, healthcare providers, insurance companies and other third-party payors in our efforts to secure reimbursement for the use of 3D tomosynthesis. However, we cannot assure 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.

Political, economic and regulatory influences, including those envisioned by the recent 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 an objective of ultimately reducing healthcare costs and expanding

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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 24, 2011, we had approximately 5,019 full-time employees, including 1,771 in manufacturing operations, 540 in research and development, 2,227 in marketing, sales and support services, and 481 in finance and administration. The non-management employees of our AEG subsidiary are represented by a union. AEG s approximate 201 non-management German employees were subject to collective bargaining agreements negotiated on a national and regional basis between Unternehmens-Verband Südöstliches Westfalen e.V., the Employers Association of North Rhine-Westphalia, and the German Metal Workers Union, IndustrieGewerkschaft Metall. In addition, AEG s German employees are represented by a works council, a Betriebsrat, with respect to various shop agreements for social matters and working conditions. We believe that our relationship with our employees is good. Except as described herein, none of our other employees are represented by a union.

Seasonality

Worldwide sales, including U.S. sales, do not reflect any significant degree of seasonality; however, customer purchases of our GYN Surgical products have been historically less in the second fiscal quarter of the year as compared to other quarters. In addition, the summer months, which is during our fiscal fourth quarter, typically have had lower order rates internationally for most of our products.

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Item 1A. Risk Factors

This report contains forward-looking information that involves risks and uncertainties, including statements regarding our plans, objectives, expectations and intentions. Such statements made in this report should be read as applicable to all forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this report.

Risks Related 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 patient s medical expenses by government healthcare programs and third-party payors. The continuing uncertainty surrounding world financial markets and continuing weak worldwide macroeconomic conditions have caused and may continue to cause the purchasers of medical equipment to decrease their medical equipment purchasing and procurement activities. 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., the Centers for Medicare & Medicaid Services, known as CMS, establish 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 Decision 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.

In November 2011, CMS announced 2012 reimbursement rates for physician, hospital and ambulatory surgical center payments. For 2011, as part of US healthcare reform legislation, which was passed on March 23, 2010, reimbursement for bone density screening in 2010 and 2011 was adjusted to 70% of the 2006 rates. This resulted in an approximate increase of 60% of the rates published in the 2010 CMS Physician Fee Schedule. However, unless future legislation is adopted, the reimbursement for bone density screening will revert in 2012 to the prior CMS

Physician Fee Schedule, which would result in an over 40% reduction in reimbursement for

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such screening, as compared to 2011 reimbursement rates. The CMS reimbursement rates for 2012 also include a general reduction of 27% in the Sustainable Growth Rate (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. Congress has, from time to time, overridden some or all of the proposed reductions in reimbursement. However, we cannot assure that Congress will override any part of the recent proposed reductions. Significant reductions in reimbursement rates proposed or implemented for the use of any our products has had and may continue to have a material adverse affect on the sales of those products.

CMS has not adopted a reimbursement rate for the use of 3D tomosynthesis, as tomosynthesis was only recently approved by the FDA in February 2011 in connection with our PMA application for our Dimensions system. We are working with governmental authorities, healthcare providers, insurance companies and other third-party payors in our efforts to secure reimbursement for the use of 3D tomosynthesis. However, we cannot assure 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 new U.S. health care reform law, adopted 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 in 2013. We expect that this excise tax will apply to our products. U.S. net product sales represented 76%, 79% and 80% of our worldwide net product sales in fiscal 2011, 2010 and 2009, respectively. Various healthcare reform proposals have also emerged at the state level. The new law 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 law and these proposals could harm our business and prospects, results of operations and/or financial condition. Public debate of these issues will likely continue in the future. 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; or
- adversely affect the use of new therapies for which our products may be targeted.

These reforms, cost containment measures and new taxes, 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.

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;

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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 the government will continue to scrutinize our industry closely and that additional regulation by governmental authorities may increase 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, during calendar 2009, the American College of Obstetricians and Gynecologists changed their recommendations for cervical cancer screening, and the United States Preventive Services Task Force (USPSTF) changed their recommendations for mammography screening, in each case, to recommend less frequent screening. On October 19, 2011, the USPSTF published draft guidelines for public comment on cervical cancer screening which may reduce the utilization of ThinPrep and / or Cervista due to recommending less frequent screening and not recommending HPV co-testing. All of these new recommendations, if implemented, could significantly reduce the amount of screening using our cervical cancer screening, mammography and related products and adversely affect the sale of those products. Moreover, the perception by the investment community or stockholders that recommendations, guidelines or studies will result in decreased use of our products could adversely affect the prevailing market price for our common stock.

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 expending significant resources on 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 FDA s approval or clearance process;

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.

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If we fail to achieve and maintain the high manufacturing standards that our products require, we may not be successful in developing and marketing those products.

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 in sufficient quantities. These difficulties have primarily related to delays and difficulties associated with ramping up production of newly introduced products and may lead to increased delivery lead-times and increased costs of manufacturing these products. 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.

Our business could be harmed if products contain undetected errors or defects or do not meet customer 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 customer 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 recall 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.

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

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 Germany, Costa Rica 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 clearance or approval by the FDA. Any modifications to a device that has received a pre-market approval that affect its safety or effectiveness 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 civic 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.

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;
- 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 addressed 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 market 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

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Dimensions 3D tomosynthesis systems are generally more 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 cannot assure that these efforts will be successful. The market for our Dimensions 3D tomosynthesis system and related products has 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. Our 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 our 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. 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 obtain FDA approval or clearance for products under development;

failure to successfully obtain approval or clearance for products in foreign countries;

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

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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;

an acquisition may result in future impairment charges related to diminished fair value of businesses acquired as compared to the price we paid for them;

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

an acquisition may involve unexpected costs or liabilities, 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 and adversely affect the market price of our common stock.

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, and may be dilutive to our stockholders. If we spend significant funds or incur additional debt or other obligations, our ability to obtain financing for working capital or other purposes could decline, and we may be more vulnerable to economic downturns and competitive pressures. We cannot guarantee that we will be able to finance additional acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

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

In connection with our acquisitions, we have incurred the obligation to make contingent earnout 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 earnout 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 earnout obligations may include covenants to operate the businesses acquired 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 business acquired. 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 earnout obligations payable in connection with the TCT and

Healthcome acquisitions will be fully expensed as accrued because our obligation to make these payments have been conditioned on the continued employment of certain key employees of TCT and Healthcome. We cannot assure 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.

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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;
- 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 our breadth in product offerings.

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

Our inability to successfully identify and complete acquisitions or successfully integrate any new or previous acquisitions could harm our business and prospects.

Our business strategy includes the acquisition of technologies and businesses that complement or augment our existing products and services. 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 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, we may not be able to integrate any acquired businesses successfully into our existing businesses, make such businesses profitable, or realize anticipated cost savings or synergies, if any, from these acquisitions, which could adversely affect our business. In addition, acquisitions in foreign countries may be more difficult to complete, integrate and operate and could adversely affect 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. 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 the ThinPrep System and our molecular diagnostic 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.

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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, copy or reverse engineer portions of our technology. We do not know if current or future patent applications will be issued with the scope of the claims sought, if at all, or whether any patents issued will be challenged or invalidated. In addition, 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 we believed 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 and related industries. We have been involved in patent litigation, and may in the future be subject to claims of infringement of intellectual property rights possessed by third parties. For further information concerning such ongoing litigation, please refer to Item 3. Legal Proceedings.

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 acquired businesses 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 trade accounts receivable collection;

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;

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- the inability to obtain favorable third-party reimbursements;
- the inability to obtain required regulatory approvals;
- governmental currency controls;
- multiple, conflicting and changing government laws and regulations (including, among other things, antitrust and tax requirements, international trade regulations and the Foreign Corrupt Practices Act);
- reduced protection for intellectual property rights in some countries;
- political and economic changes and disruptions, export/import controls and tariff regulations;
- the inability to effectively obtain or enforce intellectual property rights and otherwise protect against clone or knock off products, and;
- the lack of ability to enforce non-compete agreements with former owners of acquired businesses competing with us in China and other foreign countries.

We utilize distributors for a portion of our sales, the loss of which could harm our revenues in the territory serviced by these distributors.

We have strategic relationships with a number of key distributors for sales and service of our products, principally in foreign countries. If these strategic relationships are terminated and not replaced, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected.

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

We maintain sales and service offices outside the United States, have manufacturing facilities in Germany, Costa Rica, Canada and China and conduct business worldwide. The expenses of our international offices are denominated in local currencies, except at our Costa Rica subsidiary, where the majority of business is conducted in U.S. dollars. Our foreign sales may be denominated in local currencies, the Euro or U.S. dollar. Historically, a majority of our sales of capital equipment to international dealers have been denominated in U.S. dollars; however in the second half of fiscal 2010 we began to invoice more of our European sales in the Euro.

Fluctuations in foreign currency exchange rates could affect our revenues, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluation can result in a loss if we hold deposits of that currency. In the last few years we have not hedged foreign currency exposures, but we may in the future hedge foreign currency denominated sales. There is a risk that any hedging activities will not be successful in mitigating our foreign exchange risk exposure and may adversely impact our financial condition and results of operations.

We rely on one or only a limited number of suppliers for some key components or subassemblies for our products. This reliance could harm our business and prospects.

We rely on one or only a limited number of suppliers for some key components or subassemblies for our products. Obtaining alternative sources of supply of these components could involve significant delays and other costs and regulatory challenges, and may not be available to us on reasonable terms, if at all. The failure of a component supplier or contract assembler to provide sufficient quantities, acceptable quality and timely components or assembly service at an acceptable price, or an interruption of supplies from such a supplier could harm our business and prospects. Any disruption of supplies of key components could delay or reduce shipments, which could result in lost or deferred sales.

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

A number of companies have developed, or are expected to develop, products that compete or will compete with our products. Some of our competitors are large companies that may enjoy significant competitive advantages over us, including:

- significantly greater name recognition;
- established, or larger, distribution networks;
- additional product lines, and the ability to offer rebates or bundle products to offer discounts or incentives to gain a competitive advantage;
- higher levels of automation and more substantial installed bases of such equipment;
- more extensive research, development, sales, marketing, manufacturing and financial capabilities; and
- greater financial resources allowing them to continue to improve their technology in order to compete in an evolving industry.

The markets in which we sell our products are intensely competitive, subject to rapid technological change and may be significantly affected by new product introductions and other market activities of industry participants. Other companies may develop products that are superior to or less expensive, or both, than our products. Improvements in existing competitive products or the introductions of new competitive products may reduce our ability to compete for sales, particularly if those competitive products demonstrate better safety or effectiveness, clinical results, ease of use or lower costs.

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

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

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

Our results of operations are subject to significant quarterly variation.

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

- the overall state of healthcare and cost containment efforts;
- the timing and level of reimbursement for our products domestically and internationally;
- the development status and demand for our products;
- the development status and demand for therapies to treat the health concerns addressed by our products and treatments;
- economic conditions in our markets;
- foreign exchange rates;
- the timing of orders;
- the timing of expenditures in anticipation of future sales;
- the mix of products we sell and markets we serve;

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regulatory approval of products;

the introduction of new products and product enhancements by us or our competitors;

pricing and other competitive conditions;

unanticipated expenses;

complex revenue recognition rules pursuant to U.S. generally accepted accounting principles (U.S. GAAP);

asset impairments; and

seasonality of sales of certain of our products.

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

Recent changes to reclassify full-field digital mammography to permit 510(k) clearance could increase competition for our digital mammography products.

The FDA has down-classified 2D digital mammography systems from Class III to Class II. As a result, these systems will require a 510(k) submission rather than a PMA, which will make it easier for other mammography vendors to gain approval in the United States. We anticipate that competition in the digital mammography market will intensify as more companies and products enter this market.

Some of our activities may subject us to risks under federal and state laws prohibiting kickbacks and false or fraudulent claims.

We are subject to the provisions of a federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, which prohibit payments intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. Similarly, our international operations are subject to the provisions of the FCPA, which prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of influencing any act or decision of such official in his or her official capacity, inducing the official to do any act in violation of his or her lawful duty, or to secure any improper advantage in obtaining or retaining business. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices is ever

evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. Moreover, our failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and the imposition of civil or criminal sanctions.

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

In the ordinary course of our business we collect and store sensitive data, including intellectual property, personal information, our proprietary business information and that of our customers, suppliers and business

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partners, and personally identifiable information of our customers and employees in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. We rely on commercially available systems, software, tools and monitoring to provide security for processing, transmission and storage of confidential information. Computer hackers may attempt to penetrate our computer system and, if successful, misappropriate personal or confidential business information. In addition, an associate, contractor, or other third party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. Any such compromise of our data security and access, public disclosure, or loss of personal or confidential business information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations, damage our reputation and customers willingness to transact business with us, and subject us to additional costs and liabilities which could adversely affect our business.

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

Our business involves the risk of product liability and other claims inherent to the medical device business. If even one of our products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. We maintain product liability insurance subject to deductibles and exclusions. There is a risk that the insurance coverage will not be sufficient to protect us from product and other liability claims, or that product liability insurance will not be available to us at a reasonable cost, if at all. An under-insured or uninsured claim could harm our business and prospects. In addition, claims could adversely affect the reputation of the related product, which could damage that product s competitive position in the market.

The sale and use of our diagnostic products could also lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect that resulted in the failure to detect a disorder for which it was being used to screen, inaccurate test results or caused injuries to a patient. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure additional coverage in the future. Also, even a meritless or unsuccessful product liability claim could be time consuming and expensive to defend, which could result in a diversion of management s attention from our business and could adversely affect the perceived safety and efficacy of our products, and could harm our business and prospects.

We use hazardous materials and products.

Our research and development and manufacturing processes involve the controlled use of hazardous materials, such as toxic and carcinogenic chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by federal, state and local regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of this type of accident, we could be held liable for any resulting damages, and any such liability could be extensive. We are also subject to substantial regulation relating to occupational health and safety, environmental protection, hazardous substance control, and waste management and disposal. The failure to comply with such regulations could subject us to, among other things, fines and criminal liability.

We may incur losses in excess of our insurance coverage.

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

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

The loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operational or

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strategic objectives. Our success also depends upon our ability to attract and retain other qualified managerial and technical personnel. Competition for such personnel, particularly software engineers and other technical personnel, is intense. We may not be able to attract and retain personnel necessary for the development of our business.

Our failure to manage current or future alliances or joint ventures effectively may harm our business and prospects.

We have entered into alliances, joint ventures or other business relationships. Alliances with certain partners or companies could make it more difficult for us to enter into advantageous business transactions or relationships with others. Moreover, we may not be able to:

identify appropriate candidates for alliances or joint ventures;

assure that any alliance or joint venture candidate will provide us with the support anticipated;

successfully negotiate an alliance or joint venture on terms that are advantageous to us; or

successfully manage any alliance or joint venture.

Furthermore, any alliance or joint venture may divert management time and resources. Entering into a disadvantageous alliance or joint venture, failing to manage an alliance or joint venture effectively, or failing to comply with obligations in connection therewith, could harm our business and prospects.

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

At least annually, we review the carrying value of our goodwill, and for other long-lived assets when indicators of impairment are present, to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment of the value of these assets. Conditions that could indicate impairment and necessitate an evaluation of these assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment within which we operate. In addition, the deterioration of a company s market capitalization significantly below its net book value is an indicator of impairment. We assess goodwill for impairment at the reporting unit level and in evaluating the potential impairment of goodwill, we make assumptions regarding the amount and timing of future cash flows, terminal value growth rates and appropriate discount rates. As a result of this assessment, we recorded significant impairment charges for goodwill and intangible assets in fiscal 2009 and 2010. For further information of these charges, refer to Note 2 to our consolidated financial statements contained in Item 15 of this Annual Report.

During the fourth quarter of fiscal 2011, we performed our annual impairment test of goodwill for our reporting units, and no additional impairment charges were required. Although we use reasonable methodologies for developing assumptions and estimates underlying the fair value calculations used in our impairment tests, these estimates are uncertain by nature and can vary from actual results. It is possible that the continuation of the current global financial and economic uncertainty could negatively affect our anticipated future cash flows, or the discount

rates used to value the cash flows for each reporting unit, to such an extent that we could be required to perform an interim impairment test in fiscal 2012. We have ongoing litigation with Conceptus regarding potential patent infringement of a Conceptus patent by our Adiana system. In the first quarter of fiscal 2012, the jury returned a verdict in favor of Conceptus and awarded Conceptus $18.8 million in damages. Post trial motions will be filed addressing certain issues that could impact the ultimate outcome of this case. We also expect that Conceptus will seek to enjoin us from further sales of the Adiana system. A hearing on the post trial motions and injunctions request is scheduled for December 22, 2011. The jury verdict and any such determinations are subject to appeal by either party. If Conceptus is successful in upholding the verdict, we may be required to remove the Adiana system from the market. The jury verdict and subsequent litigation status may be an indicator of impairment for our GYN Surgical reporting unit. A reduction in the anticipated future cash flows of our GYN

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Surgical reporting unit could result in a material impairment charge that would have an adverse impact on our operating results. We will further evaluate this matter in the first quarter of fiscal 2012 and will perform an interim goodwill impairment analysis and a long-lived asset impairment analysis, if required.

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

We are subject to income taxes in both the United States and various foreign jurisdictions. We take certain income tax positions on our tax returns that we provide additional taxes if it is more likely than not they will not withstand challenge by tax authorities. We are subject to ongoing tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly evaluate the likely outcomes of these audits in order to determine the appropriateness of our tax provision and tax reserves. However, we cannot assure that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our operating results and financial condition. In addition, our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations.

Changes in tax laws or tax rulings could materially impact our effective tax rate. There are several proposals to reform U.S. tax rules being considered by U.S. law makers, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, potentially requiring those earnings to be taxed at the U.S. federal income tax rate, reduce or eliminate our ability to claim foreign tax credits, and eliminate various tax deductions until foreign earnings are repatriated to the U.S. Our future reported financial results may be adversely affected by tax rule changes which restrict or eliminate our ability to claim foreign tax credits or deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

Risks Related to our Indebtedness

We have incurred significant indebtedness that may limit our operating flexibility, and could adversely affect our operations and financial results and prevent us from fulfilling our obligations.

On December 10, 2007, we issued $1.725 billion of 2.00% convertible notes due 2037, which are unsecured and subordinated to our secured indebtedness. On November 18, 2010, we entered into separate, privately-negotiated exchange agreements under which we retired $450.0 million in aggregate principal of our Original Notes for $450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037. Following these transactions, $1.275 billion in principal amount of the Original Notes remain outstanding. Our level of indebtedness may:

- make it more difficult for us to satisfy our obligations with respect to our outstanding indebtedness;
- increase our vulnerability to general adverse economic and industry conditions, including increases in interest rates;

require us to dedicate a substantial portion of our cash flow from operations to interest and principal payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, expansion efforts and other general corporate purposes;

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

place us at a competitive disadvantage compared to our competitors that have less debt; and

limit our ability to borrow additional funds for working capital, capital expenditures, general corporate purposes or acquisitions.

If there were an event of default under our convertible notes or a change of control, the holders of the notes may be permitted to cause all amounts outstanding with respect to that debt to be due and payable immediately

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and may be cross-defaulted to other debt or obligations. Our assets or cash flow may not be sufficient to fully repay borrowings under our convertible notes, and related deferred tax liabilities, when due or if accelerated upon an event of default, and there is no guarantee that we would be able to repay, refinance or restructure the payments on that debt.

We may not be able to generate sufficient cash flow to service all of our obligations.

Our ability to make payments on our convertible notes, and related deferred tax liabilities, or any other of our obligations and to fund planned capital expenditures, strategic transactions and expansion efforts will depend on our ability to generate cash in the future. At final maturity of our convertible notes or in the event of acceleration of our convertible notes following an event of default, the entire outstanding principal amount of the convertible notes will become due and payable. In addition, each holder of our original convertible notes (aggregate principal amount of $1.275 billion) may require us to repurchase such holder s notes on December 13, 2013, and each of December 15, 2017, 2022, 2027 and 2032 or upon a fundamental change, including a change of control, and each holder of our exchange convertible notes (aggregate principal amount of $450.0 million) may require us to repurchase such holder s notes on December 15, 2016, and on each of December 15, 2020, December 15, 2025, December 13, 2030 and December 14, 2035 or upon a fundamental change. In each such case, the repurchase price would be equal to 100% of the note s accreted principal amount, plus accrued and unpaid interest. If we were unable to make the required payments or repurchases of any of our convertible notes, it would likely constitute an event of default under all the convertible notes.

Our business may not be able to generate sufficient cash flow from operations, and we cannot assure that future borrowings will be available to us in amounts sufficient to enable us to pay our indebtedness or other obligations as such indebtedness or other obligations mature or otherwise become due and to fund our other liquidity needs. If this is the case, we will need to refinance all or a portion of our indebtedness on or before maturity, and we cannot assure that we will be able to refinance any of our indebtedness on commercially reasonable terms, or at all. We may need to implement one or more alternatives, such as reducing or delaying planned expenses and capital expenditures, selling assets, restructuring debt, or obtaining additional equity or debt financing. These financing strategies may not be affected on satisfactory terms, if at all. Our ability to refinance our indebtedness or obtain additional financing, or to do so on commercially reasonable terms, will depend on, among other things, our financial condition at the time, restrictions in agreements governing our indebtedness, and other factors, including the condition of the financial markets and the markets in which we compete.

If we do not generate sufficient cash flow from operations, and additional borrowings, refinancings or proceeds of asset sales are not available to us, we may not have sufficient cash to enable us to meet all of our obligations.

Risks Related to our Common Stock and Convertible Notes

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

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

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

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

Future sales of our common stock, the perception that such sales could occur or the availability for future sales of shares of our common stock or securities convertible into or exercisable for our common stock could adversely affect the market prices of our common stock and the value of our convertible notes prevailing from time to time and could impair our ability to raise capital through future offerings of equity or equity-related securities. In addition, we may issue common stock or equity securities senior to our common stock in the future for a number of reasons, including to finance our operations and business strategy, to adjust our ratio of debt to equity, satisfy our obligations upon the exercise of options or for other reasons.

Provisions in our charter, bylaws and stockholder rights plan may have the effect of discouraging advantageous offers for our business or common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

Our charter, bylaws and the provisions of the Delaware General Corporation Law include provisions that may have the effect of discouraging or preventing a change in control. In addition, we have a stockholder rights plan that may have the effect of discouraging or preventing a change in control. These provisions could limit the price that our stockholders might receive in the future for shares of our common stock.

Our stock price is volatile.

The market price of our common stock has been, and may continue to be, highly volatile. We believe that a variety of factors could cause the price of our common stock to fluctuate, perhaps substantially, including:

- new, or changes in, recommendations, guidelines or studies that could affect the use of our products;
- announcements and rumors of developments related to our business, including changes in reimbursement rates or regulatory requirements, proposed and completed acquisitions, or the industry in which we compete;
- published studies and reports relating to the comparative efficacy of products and markets in which we participate;
- quarterly fluctuations in our actual or anticipated operating results and order levels;
- general conditions in the worldwide economy;
- announcements of technological innovations;
- new products or product enhancements by us or our competitors;

developments in patents or other intellectual property rights and litigation;

developments in relationships with our customers and suppliers;

the implementation of healthcare reform legislation and the adoption of additional reform legislation in the future, and;

the success or lack of success of integrating our acquisitions.

The price of our common stock also may be adversely affected by the amount of common stock issuable upon conversion of our Convertible Notes. In addition, in recent years the stock market in general and the markets for shares of high-tech companies, have experienced extreme price fluctuations which have often been unrelated to the operating performance of affected companies. Any such fluctuations in the future could adversely affect the market price of our common stock, and the market price of our common stock may decline.

Item 1B. Unresolved Staff Comments

None

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Item 2. Properties

We own and lease the real property identified below. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed. See the Business and Manufacturing sections above for a description of the products manufactured at the facilities described below.

Principal Properties

Owned:	Primary Use (a)	Floor Space
Newark, DE (b)	DirectRay digital detector research and development and plate manufacturing operations	164,000 sq. ft.
Warstein, Germany	AEG s manufacturing operations, research and development and administrative functions	201,000 sq. ft.
Londonderry, NH	Manufacturing operations	2.7 acres of land and 47,000 sq. ft.

Principal Properties

Leased:	Primary Use (a)	Floor Space	Lease Expiration (fiscal year)	Renewals
Bedford, MA	Headquarters, including research and development, administrative and manufacturing operations	207,000 sq. ft.	2022	4, five-yr. periods
Danbury, CT	Manufacturing facility	62,000 sq. ft.	2022	4, five-yr. periods
Marlborough, MA	Administrative, research and development, manufacturing and distribution operations	216,000 sq. ft.	2019	2, five-yr. periods
Marlborough, MA	Manufacturing operations	146,000 sq. ft.	2019	2, five-yr. periods
Danbury, CT	Manufacturing operations and research and development	60,000 sq. ft.	2013	2, five-yr. periods
Alajuela,Costa Rica	Manufacturing facility	164,000 sq. ft.	2018	2, five-yr. periods
Madison, WI	Manufacturing operations and research and development	62,000 sq. ft.	2014	None

(a) See Manufacturing section contained in Item 1 of this Annual Report for additional information regarding the products manufactured at the facilities listed.

(b) We currently occupy approximately 59,000 square feet of this building, which houses our plate manufacturing facility, including both a Class 1 and a Class 2 clean room. We lease approximately 105,000 square feet of the facility to Siemens under a lease which expires in April 2015.

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

Item 3. Legal Proceedings

On May 22, 2009, Conceptus, Inc. filed suit in the United States District Court for the Northern District of California seeking a declaration by the Court that Hologic s planned importation, use, sale or offer to sell of its forthcoming Adiana Permanent Contraception System would infringe five Conceptus patents. On July 9, 2009, Conceptus filed an amended complaint alleging infringement of the same five patents by the Adiana Permanent Contraception System. The complaint seeks preliminary and permanent injunctive relief and unspecified monetary damages. In addition to the amended complaint, Conceptus also filed a motion for preliminary injunction seeking to preliminarily enjoin sales of the Adiana System based on alleged infringement of certain claims of three of the five patents. A hearing on Conceptus preliminary injunction motion was

held on November 4, 2009, and on November 6, 2009, the judge issued an order denying the motion. On January 19, 2010, upon stipulation of the parties, the Court dismissed all claims relating to three of the five asserted patents

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with prejudice. A Markman hearing on claim construction took place on March 10, 2010 and a ruling was issued on March 24, 2010. On April 12, 2010, in response to Hologic s counterclaims of unfair competition filed in October of 2009, the Court granted Conceptus leave to amend its counterclaims adding charges of unfair competition. On June 23, 2010, upon stipulation of the parties, the Court dismissed the asserted claims of an additional patent leaving three claims of U.S. patent 7,506,650 being asserted against us in the case. On August 10, 2010, the parties entered into a settlement agreement dismissing all unfair competition claims against each other. A hearing on both parties motions for summary judgment on the patent claims occurred on December 9, 2010, and on December 16, 2010, a ruling was issued granting Hologic summary judgment of no infringement of one of the three asserted claims. A trial was held from October 3, 2011 through October 14, 2011 related to the remaining asserted claims. On October 17, 2011 the jury returned a verdict in favor of Conceptus and awarded damages to Conceptus in the amount of $18.8 million. Post trial motions will be filed addressing certain issues that could impact the ultimate outcome of the case. We also expect that Conceptus will seek to enjoin us from further sales of the Adiana system. A hearing on the post trial motions and injunction request is scheduled for December 22, 2011. The jury verdict and any such determinations are subject to appeal by either party. If Conceptus is successful in upholding the verdict, we may be required to remove the Adiana system from the market. As discussed in Note 12 to the consolidated financial statements contained in Item 15 of this Annual Report, we are indemnified for the reimbursement of qualifying legal expenses and liabilities associated with legal claims against the Adiana products and intellectual property up to a certain defined amount. We have the right to offset contingent consideration payments due to the former shareholders of Adiana, Inc., and the amount of damages awarded is accrued within accrued contingent consideration as of September 24, 2011.

On July 16, 2010 Smith & Nephew, Inc. filed suit against Interlace, which we acquired on January 6, 2011, in the United States District Court for the District of Massachusetts. In the complaint, it is alleged that the Interlace MyoSure hysteroscopic tissue removal device infringes U.S. patent 7,226,459. The complaint seeks permanent injunctive relief and unspecified damages. A Markman hearing was held November 9, 2010, and a ruling was issued on April 21, 2011. A trial on the issues has been scheduled for March 12, 2012. The purchase and sale agreement associated with our acquisition of Interlace includes an indemnification provision that provides for the reimbursement of a portion of legal expenses in defense of the Interlace intellectual property. The Company has the right to collect certain amounts set aside in escrow and, as applicable, offset contingent consideration payments of qualifying legal costs. At this time, we believe a loss is neither probable nor remote and based on available information regarding this litigation, we are unable to determine an estimate, or a range of estimates, of potential losses.

On November 22, 2011, Smith & Nephew, Inc. filed suit against Hologic in the United States District Court for the District of Massachusetts. In the complaint, it is alleged that use of the MyoSure hysteroscopic tissue removal system infringes U.S. patent 8,061,359. The complaint seeks preliminary and permanent injunctive relief and unspecified damages. The purchase and sale agreement associated with our acquisition of Interlace includes an indemnification provision that provides for the reimbursement of a portion of legal expenses associated with intellectual property claims relating to the MyoSure product. The Company has the right to collect certain amounts set aside in escrow and, as applicable, offset contingent consideration payments of qualifying legal costs. At this time, we believe a loss is neither probable nor remote and based on available information regarding this litigation, we are unable to determine an estimate, or a range of estimates, of potential losses.

On March 22, 2011, Jeffrey Schwindt filed suit against Hologic and its subsidiary, Suros Surgical Systems, Inc. in the United States District Court for the Southern District of Indiana alleging fraud, deception and misrepresentation based on Schwindt s belief that he should have been named an inventor on a Suros patent prior to the acquisition of Suros by Hologic. The complaint seeks a declaration that Schwindt is a joint inventor of the patent in question as well as unspecified monetary damages. On July 13, 2011, the fraud, misrepresentation and deception claims against Hologic were dismissed. The remaining relief requested by Schwindt regarding claims of inventorship, was administratively closed pending the outcome of an interference action in the United States Patent and Trademark office relating to the same subject matter.

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On May 10, 2011, Tissue Extraction Devices filed suit against Hologic and its subsidiary, Suros Surgical Systems, Inc., in the United States District Court for the Southern District of Indiana alleging infringement of U.S. patent 7,749,172 by the ATEC and Eviva biopsy products. The complaint seeks a finding of infringement and unspecified monetary damages. On September 2, 2011, Hologic filed a request with the United States Patent and Trademark seeking re-examination of the 172 patent. On September 22, 2011, the Parties filed a stipulation of dismissal of this case and a joint letter of agreement to halt all litigation for this matter until the re-examination is resolved. On September 23, 2011, the matter was dismissed.

We are a party to various other legal proceedings and claims arising out of the ordinary course of its business. We believe that except for those described above there are no other proceedings or claims pending against us the ultimate resolution of which would have a material adverse effect on our financial condition or results of operations.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information. Our common stock is traded on the Nasdaq Global Select Market under the symbol HOLX. The following table sets forth the high and low sales prices per share of our common stock, as reported by the Nasdaq Global Select Market.

Fiscal Year Ended September 24, 2011	High	Low
First Quarter	$ 19.00	$ 15.80
Second Quarter	21.95	18.76
Third Quarter	22.69	19.63
Fourth Quarter	20.82	15.15

Fiscal Year Ended September 25, 2010	High	Low
First Quarter	$ 16.96	$ 13.26
Second Quarter	19.72	14.46
Third Quarter	18.85	13.85
Fourth Quarter	16.93	13.22

Number of Holders. As of November 16, 2011, there were approximately 1,500 holders of record of our common stock, including multiple beneficial holders at depositaries, banks and brokers listed as a single holder in the street name of each respective depositary, bank or broker.

Dividend Policy. We have never declared or paid cash dividends on our capital stock, and we have no plans to do so. Our current policy is to retain all of our earnings to finance future growth.

Recent Sales of Unregistered Securities. We did not sell unregistered securities during the fourth quarter of fiscal 2011.

Issuer s Purchases of Equity Securities. For the majority of restricted stock units granted, the number of shares issued on the date that the restricted stock units vest is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate taxing authorities on behalf of our employees. The following table sets forth information about repurchases of our common stock to cover employee income tax withholding obligations in connection with the vesting of restricted stock units under our equity incentive plans for the three months ended September 24, 2011 (shares in thousands):

Period of Repurchase	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased As Part of Publicly Announced Plans or Program
June 26, 2011 July 23, 2011	159	$ 20.57	

July 24, 2011 August 20, 2011	65		18.57
August 21, 2011 September 24, 2011	31		15.88
Total	255	$	19.49

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Stock Performance Graph

The following graph compares cumulative total shareholder return on our common stock since September 30, 2006 with the cumulative total return of the Russell 1000 Index and the Standard & Poor s Health Care Supplies Index. This graph assumes the investment of $100 on September 30, 2006 in our common stock, the Russell 1000 Index and the S&P Health Care Supplies Index. Measurement points are the last trading day of each respective fiscal year.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Hologic, Inc., the Russell 1000 Index

and the S&P Health Care Supplies Index

* $100 invested on 9/30/06 in stock or index, including reinvestment of dividends.
Fiscal year ending September 24.

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Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, beginning on page F-1. In the second, third and fourth quarters of fiscal 2011, we acquired Interlace, TCT and Healthcome, respectively. In the fourth quarter of fiscal 2010, we acquired Sentinelle Medical. In the first and fourth quarters of fiscal 2008, we acquired Cytyc Corporation (Cytyc) and Third Wave Technologies, Inc. (Third Wave), respectively. In the fourth quarter of fiscal 2007, we acquired BioLucent, Inc. (BioLucent). Results of operations for each of these businesses are included in our consolidated financial statements from the date of acquisition.

	Fiscal Years Ended				
	September 24, 2011 (5)	September 25, 2010 (3)	September 26, 2009 (2)	September 27, 2008 (1)	September 29, 2007
	(In thousands, except per share data)				
Consolidated Statement of Operations Data					
Total revenues	$ 1,789,349	$ 1,679,552	$ 1,637,134	$ 1,674,499	$ 738,368
Total costs and expenses	$ 1,414,904	$ 1,609,615	$ 3,653,808	$ 1,872,041	$ 590,616
Net income (loss)	$ 157,150	$ (62,813)	$ (2,216,642)	$ (415,588)	$ 94,578
Basic net income (loss) per common share	$ 0.60	$ (0.24)	$ (8.64)	$ (1.69)	$ 0.88
Diluted net income (loss) per common share	$ 0.59	$ (0.24)	$ (8.64)	$ (1.69)	$ 0.86
Consolidated Balance Sheet Data					
Working capital	$ 833,450	$ 656,969	$ 489,335	$ 352,703	$ 220,568
Total assets	$ 6,008,780	$ 5,625,834	$ 5,684,226	$ 8,126,812	$ 1,066,349
Long-term debt obligations (4)	$ 1,506,448	$ 1,467,519	$ 1,536,887	$ 1,769,005	$ 9,222
Total stockholders equity	$ 2,936,895	$ 2,698,549	$ 2,725,977	$ 4,895,936	$ 805,723

(1) Included in total costs and expenses in fiscal 2008 is a charge of $370.0 million for in-process research and development from the acquisition of Cytyc and a charge of $195.2 million for in-process research and development from the acquisition of Third Wave.

(2) Included in total costs and expenses in fiscal 2009 is an aggregate goodwill impairment charge of $2.34 billion comprised of $1.17 billion for GYN Surgical, $908.3 million for Diagnostics and $265.9 million for Breast Health.

(3) Included in total costs and expenses in fiscal 2010 are impairment charges of $143.5 million for intangible assets and $76.7 million for goodwill, both of which are related to our MammoSite reporting unit within Breast Health. Also included in total costs and expenses is $11.4 million of net charges for litigation-related settlements.

(4) Long-term obligations are net of the unamortized debt discount related to our convertible notes (principal of $1.725 billion) of $236.4 million, $277.9 million, $351.1 million and $418.8 million for fiscal years 2011, 2010, 2009 and 2008, respectively.

(5) Included in total costs and expenses in fiscal 2011 is a net gain on the sale of intellectual property of $84.5 million, and included in net income in fiscal 2011 is a loss on extinguishment of debt of $29.9 million.

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

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the information described under the caption Risk Factors included elsewhere in this report.

OVERVIEW

We are a developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to the healthcare needs of women. Our core business segments are focused on Breast Health, Diagnostics, GYN Surgical and Skeletal Health.

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 (MRI) breast coils, computer-aided detection (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. We have also developed a new breast imaging platform, Dimensions, which utilizes a new technology, tomosynthesis, to produce three dimensional (3D) images, as well as conventional two dimensional (2D) full field digital mammography images. In the U.S., our Dimensions product had previously been approved by the Food and Drug Administration (FDA) for providing conventional 2D images. On February 11, 2011, we received approval from the FDA to enable the 3D tomosynthesis capability of our Dimensions system. The FDA granted approval for the use of 3D tomosynthesis in addition to a conventional 2D digital image. 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. We began to sell our Dimensions 3D tomosynthesis system in the United States immediately following FDA approval. We had been selling Dimensions 3D tomosynthesis outside of the United States in regions such as Canada, Europe, Latin America and Asia.

In August 2010, we acquired Sentinelle Medical Inc. (Sentinelle Medical), a company that develops, manufactures and markets MRI coils (including MRI breast coils), patient positioners and visualization software (MRI CAD). Sentinelle Medical, which is included within our Breast Health segment, is dedicated to developing advanced imaging technologies used in high-field strength MRI systems. In July 2011, we completed our acquisition of Beijing Healthcome Technology Company, Ltd. (Healthcome), a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China. The operations of Sentinelle Medical and Healthcome have been integrated into our Breast Health segment.

Our Diagnostics products include the ThinPrep System, which is primarily used in cytology applications such as cervical cancer screening, the Rapid Fetal Fibronectin Test, which assists physicians in assessing the risk of pre-term birth, and our molecular diagnostic reagents used for a variety of DNA and RNA analysis applications based on our proprietary Invader chemistry. Our current molecular diagnostic offerings based upon this Invader chemistry include Cervista HPV high risk (HR) and Cervista HPV 16/18 products to assist in the diagnosis of human papillomavirus (HPV), as well as other products to diagnose cystic fibrosis, cardiovascular risk and other diseases.

In June, 2011, we acquired TCT International Co., Ltd. (TCT) and subsidiaries, a privately-held distributor of medical products, including the Company s ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT s operating subsidiaries are located in Beijing, China. Our acquisition of TCT provides us with an established nationwide sales organization and customer support infrastructure in China. TCT is primarily reported within our Diagnostics segment and to a lesser extent within our GYN Surgical segment.

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

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Adiana system is a form of permanent female contraception intended as an alternative to tubal ligation. The MyoSure system was added to the GYN Surgical product portfolio as a result of our acquisition of Interlace Medical, Inc. (Interlace) on January 6, 2011. The operations of Interlace have been integrated into our GYN Surgical segment.

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.

RECENT DEVELOPMENTS

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, private insurers or other healthcare payors. The continuing uncertainty surrounding worldwide financial markets and macroeconomic conditions has caused and may continue to cause the purchasers of medical equipment to decrease or delay their medical equipment purchasing and procurement activities. Additionally, constrictions in world credit markets have caused and continue to cause our customers to experience difficulty securing the financing necessary to purchase our products. Economic uncertainty and unemployment have and may continue to result in cost-conscious consumers focusing on acute care rather than wellness, which has and may continue to adversely affect demand for our products and procedures. Furthermore, governments and other third party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could adversely affect sales of our products. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

In March 2010, significant reforms to the healthcare system were adopted as law in the United States. The law includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and imposes new and/or increased taxes. Specifically, 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 in 2013. We expect that our products will fall under the government classification requiring the excise tax. U.S. net product sales represented 76%, 79% and 80% of our worldwide net product sales in fiscal 2011, 2010 and 2009, respectively.

As we operate in a highly regulated industry, other governmental actions may adversely affect our business, operations or financial condition, including, without limitation: 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 result in lost market opportunity; changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products and treatments; new laws, regulations and judicial decisions affecting pricing or marketing practices; and changes in the tax laws relating to our operations, including those associated with the recently adopted healthcare reform law discussed above.

Professional societies, government agencies, practice management groups, private health/science foundations, and organizations involved in healthcare issues may publish guidelines, recommendations or studies to the healthcare and patient communities from time to time. 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 recently and in the past made recommendations about our products and those of our competitors. Recommendations, guidelines or studies that are followed by patients and healthcare providers could result in decreased use of our products. A number of healthcare-related organizations and agencies have issued or proposed contrasting recommendations, and some of these current recommendations could significantly reduce the amount of screening using our ThinPrep, Cervista HPV, Selenia, Dimensions and

related products and

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adversely affect the sale of those products. For example, in November 2009, the American College of Obstetricians and Gynecologists (ACOG) changed their recommendations for pap smear screening, and the United States Preventive Services Task Force (USPSTF) changed their recommendations for mammography screening, both of which recommended less frequent testing. However, in July 2011, ACOG changed its breast cancer screening guidelines recommending that mammography screening be offered annually to women beginning at age 40 instead of 50. In October 2011, the USPSTF published draft guidelines for public comment on cervical cancer screening in which they have recommended less frequent testing and no HPV co-testing.

Recently, there have been periodic significant fluctuations in foreign currencies relative to the U.S. dollar. The ongoing fluctuations of the value of the U.S. dollar, including the recent strengthening of the U.S. dollar against the Euro, may cause our products to be less competitive in international markets and may impact sales and profitability over time. Historically, a majority of our capital equipment sales to international dealers have been denominated in U.S. dollars. However, we have seen a shift of more sales being denominated in the Euro compared to the U.S. dollar for our Euro zone dealers. In addition, we have international sales, principally in our Diagnostics segment, that are denominated in foreign currencies. The value of these sales is also impacted by fluctuations in the value of the U.S. dollar. Given the uncertainty in the worldwide financial markets, foreign currency fluctuations may be significant in the future, and if the U.S. dollar continues to strengthen, we may experience a material adverse effect on our international revenues and operating results.

ACQUISITIONS

Fiscal 2011 Acquisitions:

TCT International Co., Ltd.

On June 1, 2011, we acquired TCT, a privately-held distributor of medical products, including our ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT s operating subsidiaries are located in Beijing, China. Our acquisition of TCT enabled us to obtain an established nationwide sales organization and customer support infrastructure in China as we execute on our strategy to expand internationally. The preliminary purchase price of $147.3 million is comprised of $135.0 million in cash, of which $100.0 million was paid up-front and $35.0 million plus a working capital adjustment, which has been preliminarily estimated to be $13.0 million, are deferred for one year. These amounts may be subject to further adjustment. The deferred payment has been recorded on a present value basis of $47.3 million in purchase accounting to reflect fair value and such payment is being accreted through interest expense over this one year period. In addition, the majority of the former shareholders of TCT will receive two annual contingent earn-out payments (subject to adjustment) not to exceed $200.0 million less the deferred payment. Subsequent to the acquisition date, our results of operations include the results of TCT, which are primarily reported within our Diagnostics reporting segment and to a lesser extent within our GYN Surgical reporting segment. We accounted for the TCT acquisition as a purchase of a business under Accounting Standards Codification (ASC) 805, *Business Combinations*.

The allocation of the purchase price is based upon preliminary estimates of the fair value of assets acquired and liabilities assumed as of June 1, 2011. The purchase price in excess of net tangible assets acquired was allocated to identifiable intangible assets comprised of customer relationships of $41.8 million, business licenses of $2.5 million and trade names of $1.9 million, based upon a detailed valuation that relies on projections and assumptions. The excess of the purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed was allocated to goodwill of $77.9 million.

The contingent earn-out payments are based on a multiple of incremental revenue growth for the one year periods beginning January 1, 2011 and January 1, 2012 as compared to the respective prior year periods, and are payable after the first and second anniversaries from the date of

acquisition, respectively. Since these payments are contingent on future employment, they are being recognized as compensation expense ratably over the required service periods, the first and second year anniversaries from the date of acquisition. Based on our revenue projections for the TCT business, we recorded compensation expense of $17.6 million in fiscal 2011.

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Interlace Medical, Inc.

On January 6, 2011, we acquired Interlace, a privately-held company located in Framingham, Massachusetts. Interlace is the developer, manufacturer and supplier of MyoSure. The purchase price was comprised of $126.8 million in cash (Initial Consideration), which was net of certain adjustments, plus two annual contingent payments up to a maximum of an additional $225.0 million in cash. Subsequent to the acquisition date, our results of operations include the results of Interlace, which has been integrated within our GYN Surgical reporting segment. We accounted for the Interlace acquisition as a purchase of a business under ASC 805.

The allocation of the purchase price is based upon preliminary estimates of the fair value of assets acquired and liabilities assumed as of January 6, 2011. The purchase price in excess of net tangible assets acquired was allocated to identifiable intangible assets comprised of developed technology of $158.7 million and trade names of $1.8 million, based upon a detailed valuation that relies on projections and assumptions. The excess of the purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed was allocated to goodwill of $88.3 million.

In addition to the Initial Consideration, $2.1 million was paid to certain employees upon the completion of three and six months of service from the date of acquisition. Since these payments were contingent on future employment, they were recognized as compensation expense.

The agreement includes an indemnification provision that provides for the reimbursement of a portion of legal expenses in defense of the Interlace intellectual property. We have the right to collect certain amounts set aside in escrow from the Initial Consideration and, as applicable, offset contingent consideration payments of qualifying legal costs.

The contingent payments are based on a multiple of incremental revenue growth during a two-year period following the completion of the acquisition. Pursuant to ASC 805, we have recorded an estimate of the fair value of the contingent consideration liability based on future revenue projections of the Interlace business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 15.6%. The discount rate is based on the weighted-average cost of capital of the acquired business plus a credit risk premium for non-performance risk related to the liability pursuant to ASC 820. This analysis resulted in an initial contingent consideration liability of $86.6 million, which will be adjusted periodically as a component of operating expenses based on changes in fair value of the liability driven by the accretion of the liability for the time value of money and changes in the assumptions pertaining to the achievement of the defined revenue growth milestones. This fair value measurement is based on significant inputs not observable in the market and thus represented a Level 3 measurement as defined in ASC 820, *Fair Value Measurements*. As of September 24, 2011, there were no significant changes in the estimated outcomes for the contingent consideration recognized. In connection with updating the fair value calculation for accretion as of September 24, 2011, we recorded a charge of $6.3 million in fiscal 2011 to record the liability at its fair value of $92.9 million.

Beijing Healthcome Technology Company, Ltd.

On July 19, 2011, we completed our acquisition of Healthcome, a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China. The purchase price was $9.8 million in cash, subject to adjustment, which is estimated to include a working capital reduction of $1.7 million. In addition, we are obligated to make future payments to the shareholders, who remain employed, up to an additional $7.1 million over three years. Since these payments are contingent on future employment, they are being recognized as compensation expense ratably over the respective service periods. Based on the terms of the contingent consideration arrangements, we recorded $0.3 million of compensation expense in fiscal 2011.

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The allocation of the purchase price is based upon preliminary estimates of the fair value of assets acquired and liabilities assumed as of July 19, 2011. The purchase price in excess of net tangible assets acquired was allocated to identifiable intangible assets comprised of developed technology of $2.8 million, in-process research and development of $0.8 million and trade names of $0.2 million, based upon a detailed valuation that relies on projections and assumptions. The excess of the purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed was allocated to goodwill of $5.8 million.

Fiscal 2010 Acquisitions:

Sentinelle Medical Inc.

On August 5, 2010, we acquired Sentinelle Medical, a privately held company located in Toronto, Canada. The purchase price was comprised of an $84.8 million cash payment, which was net of certain adjustments, plus three contingent payments over a two-year period up to a maximum of an additional $250.0 million in cash. Subsequent to the acquisition date, our results of operations include the results of Sentinelle Medical, which is a component of our Breast Health reporting segment. We accounted for the Sentinelle acquisition as a purchase of a business under ASC 805.

The allocation of the purchase price was based upon estimates of the fair value of assets acquired and liabilities assumed as of August 5, 2010. The purchase price in excess of net tangible assets acquired was allocated to identifiable intangible assets aggregating $67.6 million, primarily comprised of developed technology of $60.9 million and in-process research and development projects of $4.8 million, based upon a detailed valuation that relies on projections and assumptions. The excess of the purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed was allocated to goodwill of $48.6 million.

The amount allocated to acquired in-process research and development represented the estimated fair value of in-process projects based on risk-adjusted cash flows utilizing a discount rate of 17%. These in-process projects had not yet reached technological feasibility and had no future alternative uses as of the date of the acquisition. The primary basis for determining the technological feasibility of these projects was obtaining regulatory approval to market the underlying products. The acquired in-process research and development assets are not subject to amortization until the projects are complete, at which time, they will be amortized over their estimated remaining useful lives ranging from 10 to 20 years. These projects relate to a prostate MRI coil and certain software. We received FDA approval for both projects in fiscal 2011.

The contingent payments are based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition. Pursuant to ASC 805, we have recorded an estimate of the fair value of the contingent consideration liability based on future revenue projections of the Sentinelle Medical business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 16.5%. The discount rate is based on the weighted-average cost of capital of the acquired business plus a credit risk premium for non-performance risk related to the liability pursuant to ASC 820. This analysis resulted in an initial contingent consideration liability of $29.5 million, which will be adjusted periodically as a component of operating expenses based on changes in fair value of the liability driven by the accretion of the liability for the time value of money and changes in the assumptions pertaining to the achievement of the defined revenue growth milestones. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820.

During each quarter in fiscal 2011, we have re-evaluated our assumptions and updated the revenue and probability assumptions for future earn-out periods and lowered our projections. As a result of these adjustments, which were partially offset by the accretion of the liability using a current discount rate of approximately 17.0%, we recorded a reversal of expense of $14.3 million in fiscal 2011 to record the contingent

consideration liability at fair value. In addition, during the second quarter of fiscal 2011, the first earn-out period ended, and we adjusted the fair value of the contingent consideration liability for actual results during the earn-out period. This payment of $4.3 million was made in the third quarter of fiscal 2011. At September 24, 2011, the fair value of the liability is $10.9 million.

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RESULTS OF OPERATIONS

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

	Fiscal Years Ended		
	September 24, 2011	September 25, 2010	September 26, 2009
Revenues:			
Product sales	82.6%	84.2%	87.2%
Service and other revenues	17.4	15.8	12.8
	100.0	100.0	100.0
Costs and expenses:			
Cost of product sales	29.1	29.0	28.3
Cost of product sales amortization of intangible assets	9.9	10.2	9.5
Cost of product sales impairment of intangible assets		7.3	0.2
Cost of service and other revenues	9.4	9.6	9.6
Research and development	6.5	6.2	6.3
Selling and marketing	16.0	14.7	14.6
General and administrative	8.9	8.8	8.6
Amortization of intangible assets	3.3	3.3	3.1
Contingent consideration compensation expense	1.1		
Contingent consideration fair value adjustments	(0.4)		
Impairment of goodwill		4.6	142.9
Impairment of intangible assets		1.2	
Gain on sale of intellectual property, net	(4.7)		
Litigation-related settlement charges, net		0.7	
Acquired in-process research and development		0.1	
Restructuring and divestiture charges, net		0.1	
	79.1	95.8	223.2
Income (loss) from operations	20.9	4.2	(123.2)
Interest income	0.1	0.1	0.1
Interest expense	(6.4)	(7.6)	(8.2)
Loss on extinguishment of debt	(1.7)		
Other (expense) income, net	(0.2)	0.1	(0.2)
Income (loss) before income taxes	12.7	(3.2)	(131.5)
Provision for income taxes	3.9	0.5	3.9
Net income (loss)	8.8%	(3.7)%	(135.4)%

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Fiscal Year Ended September 24, 2011 Compared to Fiscal Year Ended September 25, 2010

Product Sales.

	Years Ended					
	September 24, 2011		September 25, 2010		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Sales						
Breast Health	$ 550,112	31%	$ 525,622	31%	$ 24,490	5%
Diagnostics	566,349	32%	548,832	33%	17,517	3%
GYN Surgical	299,120	17%	281,364	17%	17,756	6%
Skeletal Health	62,759	3%	59,082	3%	3,677	6%
	$ 1,478,340	83%	$ 1,414,900	84%	$ 63,440	4%

In fiscal 2011, our product sales increased $63.4 million, or 4%, compared to fiscal 2010 due to an increase in revenues of $24.5 million from Breast Health, $17.8 million from GYN Surgical, $17.5 million from Diagnostics, and $3.7 million from Skeletal Health.

Breast Health product sales increased 5% in fiscal 2011 compared to fiscal 2010 primarily due to growth in our breast biopsy products of $16.8 million, the inclusion of a full year of revenues from Sentinelle Medical (acquired in the fourth quarter of fiscal 2010), which increased $12.9 million, and a favorable foreign currency impact of $3.4 million. The increase in breast biopsy products revenue is primarily attributable to an increase in the number of Eviva biopsy devices sold with the largest increase in the U.S. Overall, our digital mammography systems revenues decreased $2.9 million in fiscal 2011 compared to fiscal 2010. We experienced a decrease in the number of Selenia systems sold worldwide, and to a lesser extent, Selenia product mix and configuration differences resulted in lower revenues in fiscal 2011 compared to fiscal 2010. We sold a greater number of our Selenia value-related models and a lesser amount of our full featured Selenia models in fiscal 2011. Our value-related models have lower average selling prices than our full featured Selenia models. In addition, we sold more Selenia systems internationally as a percentage of total Selenia systems and average selling prices are lower in our international markets compared to the domestic market. Mostly offsetting these decreases was an increase in the number of units sold of our new 2D/3D Dimensions products as these systems continue to gain traction. These systems also have higher average selling prices than our Selenia systems. We expect the shift in sales from our Selenia to our Dimensions products to continue as we received FDA approval of our 3D tomosynthesis capability in February 2011.

Diagnostics product sales increased 3% in fiscal 2011 compared to fiscal 2010 primarily due to an increase in revenues from our Cervista HPV tests, the inclusion of TCT (acquired in the third quarter of fiscal 2011) resulting in incremental revenues of approximately $10 million, a favorable foreign currency impact of $5.2 million and to a lesser extent an increase in the number of ThinPrep pap tests sold internationally, partially offset by a reduction in domestic sales. Cervista HPV revenues have increased as we continue to gain new customer accounts and unit sales to existing customers increase. We believe the decline in the number of ThinPrep pap tests sold domestically is due to the decline in patient visits year over year attributable to the lagging effects of unemployment, continuing economic uncertainty, recent changes in cervical cancer screening guidelines to extend the recommended intervals between such screenings, and to a lesser extent laboratory consolidation.

GYN Surgical product sales increased 6% in fiscal 2011 compared to fiscal 2010 due to an increase in the number of Adiana systems sold and the inclusion of MyoSure system sales (acquired in the second quarter of fiscal 2011). NovaSure system sales were essentially flat year over year. While we experienced an increase in the number of NovaSure devices sold internationally and to a lesser extent a slight increase in average selling prices, these increases were offset by a decline in the number of NovaSure devices sold domestically. We believe the decline in units sold domestically is due to the lagging effects of unemployment and continuing economic uncertainty, which has resulted in patients delaying surgery

and opting for lower cost and generally less effective alternatives.

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Skeletal Health product sales increased 6% in fiscal 2011 compared to fiscal 2010 primarily due to a $6.0 million increase in osteoporosis assessment product sales worldwide. Offsetting this increase in fiscal 2011 was a reduction in mini C-arm revenues of $2.1 million due to a decrease in the number of units sold domestically and slightly lower average selling prices in fiscal 2011 compared to fiscal 2010.

In fiscal 2011, 76% of product sales were generated in the United States, 13% in Europe, 6% in Asia-Pacific, and 5% in other international markets. In fiscal 2010, 79% of product sales were generated in the United States, 12% in Europe, 5% in Asia-Pacific, and 4% in other international markets.

Service and Other Revenues.

	Years Ended					
	September 24, 2011		September 25, 2010		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$ 311,009	17%	$ 264,652	16%	$ 46,357	18%

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. Service and other revenues increased 18% in fiscal 2011 compared to fiscal 2010 primarily in our Breast Health business due to an increase in the number of service contracts driven by an increase in our installed base of our digital mammography systems, which are no longer under warranty.

Cost of Product Sales.

	Years Ended					
	September 24, 2011		September 25, 2010		Change	
	Amount	% of Product Sales	Amount	% of Product Sales	Amount	%
Cost of Product Sales	$ 521,189	35%	$ 487,057	34%	$ 34,132	7%
Cost of Product Sales Amortization of Intangible Assets	177,456	12%	171,447	12%	6,009	4%
Cost of Product Sales Impairment of Intangible Assets			123,350	9%	(123,350)	(100)%
	$ 698,645	47%	$ 781,854	55%	$ (83,209)	(11)%

Product sales gross margin increased to 53% in fiscal 2011 compared to 45% in fiscal 2010 primarily due to the significant intangible asset charge of $123.4 million recorded in fiscal 2010 related to MammoSite.

Cost of Product Sales. The cost of product sales as a percentage of product sales was 35% in fiscal 2011 compared to 34% in fiscal 2010. In fiscal 2011, cost of product sales as a percentage of product revenues increased in Breast Health compared to fiscal 2010 and was relatively flat

in Diagnostics, GYN Surgical and Skeletal Health compared to fiscal 2010. The decline in Breast Health gross margin in fiscal 2011 was primarily due to $2.7 million of additional costs related to the sale of acquired Sentinelle Medical inventory written up to fair value in purchase accounting, unfavorable absorption and higher production spend principally in the digital mammography product lines, and a mix shift in sales of our Selenia product line. Our Selenia value-related models have lower average selling prices and gross margins than our full featured Selenia models. In addition, we sold more Selenia systems internationally as a percentage of total Selenia systems, where our average selling prices are lower. Partially offsetting these decreases were higher sales of Dimensions 3D and 3D tomosynthesis software upgrades. The Dimensions 3D product has a higher average selling price and gross margin compared to

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our full-featured Selenia models. Within our breast biopsy products, the mix of products sold resulted in lower gross margins as we sold more Eviva disposables and less ATEC disposables as a percentage of revenue compared to fiscal 2010. Eviva disposables have a lower gross margin than our ATEC disposables because they have a higher manufacturing cost and carry additional royalty charges.

Cost of Product Sales Amortization of Intangible Assets. Amortization of intangible assets relates to acquired developed technology. These intangible assets are generally amortized over their estimated useful lives of between 8.5 and 20 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed. The economic pattern is based on undiscounted future cash flows. The increase in amortization expense in fiscal 2011 compared to fiscal 2010 was primarily due to the inclusion of additional amortization expense related to the technology assets acquired from the Sentinelle Medical and Interlace acquisitions in the fourth quarter of fiscal 2010 and second quarter of fiscal 2011, respectively. In addition, there was an increase in amortization expense in the current year due to the method of recognition based on the expected economic benefits of the underlying assets, primarily related to the intangible assets acquired in the Cytyc merger in the first quarter of fiscal 2008. Offsetting this increase was a decline in amortization expense in fiscal 2011 related to our MammoSite reporting unit. We recorded an impairment charge for its developed technology in the fourth quarter of fiscal 2010, as discussed below, resulting in a reduced asset value and lower future amortization expense.

Cost of Product Sales Impairment of Intangible Assets. During the fourth quarter of fiscal 2010 in connection with our Company-wide annual budgeting and strategic planning process, we identified indicators of impairment in our MammoSite reporting unit due to changing market conditions for the breast brachytherapy market, including downward pressure on procedure volumes from the continuing adverse macroeconomic environment and current trends in breast cancer management, as well as competitive pricing pressures and competition from existing and alternative new technologies. These factors resulted in lowering our financial projections for MammoSite. We performed the first step in the long-lived assets impairment test and compared MammoSite s forecasted undiscounted cash flows to the carrying value of its net assets, which indicated that these cash flows were insufficient to recover MammoSite s carrying value. Therefore, we determined the fair value of MammoSite s long-lived assets, which are primarily intangible assets, using a discounted cash flow technique. Based on the fair value of the long-lived assets, we recorded an impairment charge of $123.4 million to developed technology in the fourth quarter of fiscal 2010. For additional information, refer to Note 2 to the consolidated financial statements contained in Item 15 of this Annual Report.

Cost of Service and Other Revenues.

	Years Ended					
	September 24, 2011		September 25, 2010		Change	
	Amount	% of Service and Other Revenues	Amount	% of Service and Other Revenues	Amount	%
Cost of Service and Other Revenues	$ 167,523	54%	$ 161,060	61%	$ 6,463	4%

Service and other revenues gross margin has improved to 46% in fiscal 2011 compared to 39% in fiscal 2010 primarily due to the improved absorption of fixed service costs and the continued growth of service contract revenue, primarily in the Breast Health business. We have been able to convert a high percentage of our domestic installed base of digital mammography systems to service contracts upon the expiration of the warranty period. In addition, warranty costs have decreased due to lower failure rates in certain of our products.

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Operating Expenses.

	Years Ended					
	September 24, 2011		September 25, 2010		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$ 116,696	7%	$ 104,305	6%	$ 12,391	12%
Selling and marketing	286,730	16%	247,374	15%	39,356	16%
General and administrative	158,793	9%	148,340	9%	10,453	7%
Amortization of intangible assets	58,334	3%	54,858	3%	3,476	6%
Contingent consideration compensation expense	20,002	1%			20,002	100%
Contingent consideration fair value adjustments	(8,016)	0%			(8,016)	(100)%
Impairment of goodwill			76,723	5%	(76,723)	(100)%
Impairment of intangible assets			20,117	1%	(20,117)	(100)%
Gain on sale of intellectual property, net	(84,502)	(5)%			(84,502)	(100)%
Litigation settlement charges, net	770	0%	11,403	1%	(10,633)	(93)%
Acquired in-process research and development			2,000	0%	(2,000)	(100)%
Restructuring and divestiture charges, net	(71)	0%	1,581	0%	(1,652)	(104)%
	$ 548,736	31%	$ 666,701	40%	$ (117,965)	(18)%

Research and Development Expenses. Research and development expenses increased 12% in fiscal 2011 compared to fiscal 2010. The increase was primarily due to the inclusion of additional expenses from Sentinelle Medical (acquired in the fourth quarter of fiscal 2010) and Interlace (acquired in the second quarter of fiscal 2011). In the current year, compensation and benefits increased due to an increase in headcount, annual salary increases, and higher bonuses based on improved company performance compared to the prior year. In addition, there was an increase in clinical trials and research projects spend primarily attributable to next generation NovaSure and Adiana products, partially offset by a reduction in clinical trial and project spend on the Dimensions 3D tomosynthesis product, which was approved by the FDA in February 2011. Research and development primarily reflects spending on new product development programs, regulatory compliance and clinical research and trials. At any point in time, we have a number of different research projects and clinical trials being conducted and the timing of these projects and related costs can vary period to period.

Selling and Marketing Expenses. Selling and marketing expenses increased 16% in fiscal 2011 compared to fiscal 2010. This increase was primarily due to additional expenses from the inclusion of Sentinelle Medical, Interlace and TCT, expenditures for our direct-to-consumer advertising campaign for the NovaSure system, higher spending for other marketing and advertising initiatives including the Dimensions 3D product launch, increased compensation and benefits related to an increase in headcount, annual salary increases and higher bonuses based on improved company performance compared to the prior year, and medical education. Partially offsetting these increases were lower distributor and third-party commissions.

General and Administrative Expenses. General and administrative expenses increased 7% in fiscal 2011 compared to fiscal 2010 primarily due to additional expenses from the inclusion of Sentinelle Medical, Interlace and TCT, an increase in compensation and benefits primarily due to an increase in headcount, annual salary increases, higher bonuses due to improved company performance compared to the prior year, and additional expenses related to consummating our acquisitions and integrating them into our operations, including

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accounting and tax services. In the current year, these increases were partially offset by a decrease in litigation costs due to lower activity compared to fiscal 2010, in which a number of matters were resolved, primarily the Ethicon lawsuit.

Amortization of Intangible Assets. Amortization of intangible assets results from customer relationships, trade names, business licenses and non-compete agreements related to our acquisitions. These intangible assets are generally amortized over their estimated useful lives of between 2 and 30 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed. The increase in fiscal 2011 compared to fiscal 2010 is due to the addition of intangible assets from the Sentinelle Medical, Interlace and TCT acquisitions, and an increase in amortization due to the method of recognition based on the expected economic benefits of the underlying assets, primarily related to the intangible assets acquired in the Cytyc merger in the first quarter of fiscal 2008.

Contingent Consideration Compensation Expense. In connection with our recent acquisitions, we are obligated to make contingent earn-out payments. Amounts recorded in this financial statement line item are those contingent payments that are contingent on future employment. These payments are also generally based on achieving certain performance milestones, typically incremental revenue growth, as is the case for TCT. The amounts recorded related to Interlace and Healthcome are solely related to continuing employment. In fiscal 2011, we recorded an aggregate charge of $20.0 million comprised of $17.6 million, $2.1 million and $0.3 million related to TCT, Interlace and Healthcome, respectively. For additional information, refer to Note 3 to the consolidated financial statements contained in Item 15 of this Annual Report.

Contingent Consideration Fair Value Adjustments. In connection with the purchase price allocation for our acquisitions of Sentinelle Medical and Interlace, we recorded an estimate of the fair value of the contingent consideration liability for each acquisition as required by U.S. generally accepted accounting principles. This liability is not contingent on future employment and is based on future revenue projections of the respective businesses under various potential scenarios and weighted probability assumptions of these outcomes. This analysis is updated quarterly and changes to the fair value of this liability are recorded in the statements of operations. As a result, we recorded a net credit of $8.0 million in fiscal 2011 reflecting a net decrease in the fair values of these liabilities comprised of reduction in the fair value of the Sentinelle Medical liability of $14.3 million due primarily to changes in revenue assumptions offset by a charge of $6.3 million related to Interlace based primarily on the accretion of the liability to the expected payment amount. For additional information, refer to Note 3 to the consolidated financial statements contained in Item 15 of this Annual Report.

Impairment of Goodwill. During the fourth quarter of fiscal 2010, in connection with performing our Company-wide annual budgeting and forecasting process, we determined that there were indicators of impairment related to our MammoSite reporting unit, and we recorded intangible asset impairment charges discussed above and below. The fair value of this reporting unit declined from fiscal 2009 primarily due to our reassessment of the overall market size of breast brachytherapy and a reduction in long-term growth projections. After determining the fair values of MammoSite s long-lived assets, other than goodwill, and writing these assets down to their fair values, we performed the 2-step goodwill impairment test for MammoSite. As a result of this analysis, we recorded a $76.7 million goodwill impairment charge. No other reporting units were deemed to be impaired in fiscal 2010. For additional information, refer to Note 2 Intangible Assets and Goodwill to the consolidated financial statements contained in Item 15 of this Annual Report.

Impairment of Intangible Assets. As noted above under Cost of Product Sales Impairment of Intangible Assets, in fiscal 2010, we determined that the long-lived assets in the MammoSite reporting unit were impaired. As a result of this analysis, we recorded a $20.1 million charge in fiscal 2010 to write down customer relationships and trade name intangible assets to their fair values. For additional information, refer to Note 2 Intangible Assets and Goodwill to the consolidated financial statements contained in Item 15 of this Annual Report.

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Gain on Sale of Intellectual Property, Net. During the second quarter of fiscal 2011, we received FDA approval of Makena, formerly known as Gestiva, and all rights to Makena were transferred to K-V Pharmaceutical Company (KV) pursuant to our agreement in which we sold the exclusive worldwide rights of Makena to KV. Upon transfer, we received $12.5 million, and including the $79.5 million received in prior years, we recorded a gain on the sale of intellectual property, net of the write-off of certain assets, of $84.5 million in the second quarter of fiscal 2011. For additional information on this arrangement and amounts we may receive in the future, refer to Note 4 to the consolidated financial statements contained in Item 15 of this Annual Report.

Litigation Settlement Charges, Net. In fiscal 2011, we incurred a charge of $0.8 million relating to the settlement of three insignificant cases. In fiscal 2010, we incurred litigation settlement charges of $11.4 million primarily relating to our litigation with Ethicon Endo-Surgery, Inc. (Ethicon). We had been engaged in litigation in which Ethicon had alleged patent infringement by our ATEC biopsy system of certain of their patents, and Ethicon had made similar claims of our Eviva biopsy system. On February 17, 2010, we entered into a settlement agreement with Ethicon, and all outstanding litigation between the parties was dismissed. In connection with the settlement agreement, we agreed to make a one-time payment to Ethicon of $12.5 million and ongoing royalties for sales of our ATEC and Eviva products, and Ethicon agreed to pay us ongoing royalties for sales of its Mammotome magnetic resonance imaging product.

Acquired In-Process Research and Development. During the fourth quarter of fiscal 2010, we acquired certain assets that were determined to have no future alternative use and recorded a $2.0 million charge within our Diagnostics segment.

Restructuring and Divestiture Charges, Net. During the fourth quarter we terminated the employment of certain employees and recorded a severance benefits charge of $0.3 million, which was offset by a gain of $0.4 million related to the sale of an insignificant product line. During the fourth quarter of fiscal 2010, we terminated the employment of certain employees in connection with completing the Sentinelle Medical acquisition and recorded severance and related benefit costs of $0.9 million. During the second quarter of fiscal 2010, we completed the sale of the capital stock of our organic photoconductor drum coating manufacturing operation in Shanghai, China for a net sales price of $3.8 million resulting in a loss on disposal of $0.3 million. As a result of previously closing this facility, we incurred additional net charges of $0.4 million in fiscal 2010.

Interest Income.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Interest Income	$ 1,860	$ 1,278	$ 582	46%

Interest income increased in fiscal 2011 compared to fiscal 2010 primarily due to an increase in cash and cash equivalents.

Interest Expense.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%

Interest Expense	$ (114,846)	$ (127,107)	$ (12,261)	(10)%

In fiscal 2011, interest expense consists primarily of the interest costs and the related amortization of the debt discount of our Convertible Notes as well as the amortization of deferred financing costs. In fiscal 2010, in

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addition to the interest expense related to our Convertible Notes, we incurred interest costs and the amortization of deferred financing costs related to our senior secured credit agreement. The amounts outstanding under our senior secured credit agreement were paid off in the third quarter of fiscal 2010, and we terminated the agreement.

Loss on Extinguishment of Debt

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Loss on Extinguishment of Debt	$ (29,891)	$	$ (29,891)	(100)%

In the first quarter of fiscal 2011, pursuant to separate, privately-negotiated exchange agreements, we retired $450.0 million in aggregate principal of our Convertible Notes for $450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037. This exchange enabled us to extend the first put date three years to December 15, 2016 from December 13, 2013 as well as the subsequent put dates as disclosed in the Liquidity and Capital Resources section of this Management s Discussion and Analysis. In consideration, the equity conversion price of the notes was reduced to $23.03 from $38.60, and we must pay the cash coupon for three more years, consistent with extending the first put date, instead of accreting the coupon to the principal as required under the original terms. In connection with this transaction, we recorded a loss on extinguishment of debt of $29.9 million, which includes the write-off of the pro-rata allocation of deferred financing costs. For additional information, refer to Note 5 to the consolidated financial statements contained in Item 15 of this Annual Report.

Other (Expense) Income, net.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Other (Expense) Income, net	$ (4,182)	$ 901	$ (5,083)	(564)%

In fiscal 2011, this account is primarily comprised of impairment charges of $2.4 million for cost-method investments, net foreign currency transaction losses of $1.1 million and a loss on cash surrender value of life insurance contracts related to our Nonqualified Deferred Compensation Plan (DCP) of $0.8 million, which is driven by the underlying changes in the stock market. In fiscal 2010, this account was primarily comprised of an increase in the cash surrender value of life insurance contracts related to our DCP of $1.3 million and an increase related to non-income tax related government credits of $0.8 million partially offset by an impairment charge of $1.1 million for a cost-method investment.

Provision for Income Taxes.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Provision for Income Taxes	$ 70,236	$ 7,822	$ 62,414	798%

Our effective tax rate for fiscal 2011 was 30.9% of pre-tax earnings compared to 14.2% of the pre-tax loss in fiscal 2010. The effective tax rate in fiscal 2011 was less than the statutory rate primarily due to the reversal of income tax reserves, the Section 199 manufacturing deduction for domestic production activities, and U.S. and

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Canadian research and development tax credits. The reversal of $9.1 million of income tax reserves was due to the closure of the United States Internal Revenue Service federal audit for fiscal years 2007, 2008 and 2009 and the expiration of the statute of limitations in various domestic (federal and state) and foreign jurisdictions. Our effective tax rate for fiscal 2010 was significantly impacted by the $76.7 million goodwill impairment charge recorded in the fourth quarter, substantially all of which was not deductible for tax purposes.

We anticipate an effective tax rate of approximately 48% of pre-tax earnings in fiscal 2012.

Segment Results of Operations

We report our business as four segments: Breast Health, Diagnostics, GYN Surgical and Skeletal Health. The accounting policies of the segments are the same as those described in the footnotes to the accompanying consolidated financial statements contained in Item 15 of this Annual Report. We measure segment performance based on total revenues and operating income or loss. Revenues from product sales of each of these segments are described in further detail above. The discussion that follows is a summary analysis of total revenues and the primary changes in operating income or loss by segment.

Breast Health.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 825,551	$ 755,542	$ 70,009	9%
Operating Income (Loss)	$ 187,970	$ (93,623)	$ 281,593	301%
Operating Income (Loss) as a % of Segment Revenue	23%	(12)%		

Breast Health revenues increased in fiscal 2011 compared to fiscal 2010 primarily due to a $45.5 million increase in service revenues that is substantially related to additional service contracts for the increased number of digital mammography systems in our installed base and the increase in product revenues of $24.5 million discussed above.

Operating income for this business segment increased $281.6 million in fiscal 2011 compared to fiscal 2010 primarily due to a $220.2 million intangible asset and goodwill impairment charge related to our MammoSite reporting unit recorded in the fourth quarter of fiscal 2010 discussed above. The balance of the increase in fiscal 2011, $61.4 million, was primarily due to increased gross margin on an absolute dollar basis as a result of higher product and service revenues as discussed above and lower operating expenses. Overall the gross margin rate as a percentage of revenues increased to 49.0% in fiscal 2011 compared to 30.7% in fiscal 2010 primarily due to the $123.4 million impairment charge to MammoSite s developed technology included in fiscal 2010. In addition, in fiscal 2011, there have been improvements in service gross margins and lower intangible asset amortization expense resulting from the write-off of MammoSite intangibles in the fourth quarter of fiscal 2010. In fiscal 2010, overall gross margin, excluding the impact of the MammoSite impairment charge, was 47.0%.

Operating expenses for this business segment decreased $108.8 million in fiscal 2011 compared to fiscal 2010 primarily due to the impact of the goodwill and intangible asset charge of $96.8 million recorded in operating expenses in fiscal 2010. Other operating expense decreases in fiscal 2011 included a net credit of $14.3 million related to adjusting the Sentinelle Medical contingent consideration to fair value, lower clinical trials spending related to our Dimensions 3D tomosynthesis system, lower third-party commissions, lower intangible asset amortization from the write-off of MammoSite intangibles in the fourth quarter of fiscal 2010, and a decrease in litigation costs. In the second quarter of fiscal 2010, we recorded a litigation settlement charge of $12.5 million as discussed above. Partially offsetting these operating expense decreases was the inclusion of a

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full year of expenses for Sentinelle Medical (acquired in the fourth quarter of fiscal 2010), and higher compensation costs related to hiring additional personnel, annual salary increases, higher bonuses due to improved company performance and higher sales commissions for our breast biopsy business.

Diagnostics.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 571,263	$ 552,501	$ 18,762	3%
Operating Income	$ 170,693	$ 100,469	$ 70,224	70%
Operating Income as a % of Segment Revenue	30%	18%		

Diagnostics revenues increased in fiscal 2011 compared to fiscal 2010 primarily due to the increase in product sales discussed above.

Operating income increased in fiscal 2011 compared to fiscal 2010 primarily due to the net gain of $84.5 million on the sale of the Makena intellectual property to KV in the second quarter of fiscal 2011 discussed above and an increase in gross margin in absolute dollars due to higher revenues. Gross margin rates were 53.9% and 53.4% in fiscal 2011 and 2010, respectively. These increases were partially offset by higher operating expenses attributable to the inclusion of TCT (acquired in the third quarter of fiscal 2011) and related integration costs and contingent consideration compensation expense of $17.6 million, and higher compensation costs related to hiring additional personnel, annual salary increases, and higher bonuses due to improved company performance.

GYN Surgical.

	Years Ended			
	September 24, 2011	September 25, 2010	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 300,538	$ 283,142	$ 17,396	6%
Operating Income	$ 3,623	$ 53,071	$ (49,448)	(93)%
Operating Income as a % of Segment Revenue	1%	19%		

GYN Surgical revenues increased in fiscal 2011 compared to fiscal 2010 primarily due to the increase in product sales discussed above.

Operating income decreased in fiscal 2011 compared to fiscal 2010 primarily due to the inclusion of Interlace s operations (acquired in the second quarter of fiscal 2011), including intangible asset amortization expense, a charge of $6.3 million to adjust the Interlace contingent consideration liability to fair value and a charge of $2.1 million to record Interlace contingent consideration compensation expense as payments

were tied to continuing employment. Overall, gross margin in absolute dollars decreased slightly in fiscal 2011 compared to fiscal 2010. This segment s gross margin rates declined to 56.8% compared to 61.0% in fiscal 2010, primarily due to higher intangible asset amortization expense. In addition, this segment incurred higher operating expenses, principally in sales and marketing for increased advertising of the Novasure system, including expenditures related to our direct-to-consumer advertising campaign, an increase in compensation and benefits related to hiring additional personnel, annual salary increases, and higher bonuses due to improved company performance, increased amortization expense from intangible assets, and higher project expense on the development of next generation products. In addition, the first quarter of fiscal 2010 included the reversal of stock compensation due to the departure of a senior executive.

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Skeletal Health.

	Years Ended		Change	
	September 24, 2011 Amount	September 25, 2010 Amount	Amount	%
Total Revenues	$ 91,997	$ 88,367	$ 3,630	4%
Operating Income	$ 12,159	$ 10,020	$ 2,139	21%
Operating Income as a % of Segment Revenue	13%	11%		

Skeletal Health revenues increased in fiscal 2011 compared to fiscal 2010 primarily due to the increase in product sales discussed above.

Operating income increased in fiscal 2011 compared to fiscal 2010 primarily due to the increase in revenues and improvement in gross margin rates to 43.5% compared to 42.4% in the prior year. Operating expenses remained relatively flat.

Fiscal Year Ended September 25, 2010 Compared to Fiscal Year Ended September 26, 2009

Product Sales.

	Years Ended					
	September 25, 2010		September 26, 2009		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Product Sales						
Breast Health	$ 525,622	31%	$ 553,065	34%	$ (27,443)	(5)%
Diagnostics	548,832	33%	544,143	33%	4,689	1%
GYN Surgical	281,364	17%	263,187	16%	18,177	7%
Skeletal Health	59,082	3%	66,591	4%	(7,509)	(11)%
	$ 1,414,900	84%	$ 1,426,986	87%	$ (12,086)	(1)%

In fiscal 2010, our product sales decreased $12.1 million, or 1%, compared to fiscal 2009 primarily due to a decrease of $27.4 million in our Breast Health products and to a lesser extent a $7.5 million decline in Skeletal Health products partially offset by increases in GYN Surgical and Diagnostic products of $18.2 million and $4.7 million, respectively.

Breast Health product sales decreased 5% in fiscal 2010 compared to fiscal 2009 primarily due to a $13.9 million decline in digital mammography systems revenues principally due to product mix as we sold a greater number of defeatured Selenia systems, which have lower average selling prices than our full featured models, a shift to a higher level of international sales, and to a lesser extent, we experienced slight pressure on average selling prices. These decreases were partially offset by an increase in the number of units sold of our new 2D/3D

Dimensions systems. The decline in revenue is also due to phasing out the supply of digital detectors to an OEM and closing our AEG organic photoconductor drum coatings manufacturing operations in Shanghai, which in aggregate accounted for $17.5 million in revenues in fiscal 2009. These decreases were partially offset by a $9.3 million increase in revenues due to higher volumes of our breast biopsy products, offset in part by a slight reduction in average selling prices for these products. We also generated $2.4 million in revenues from sales of MRI breast coils through our acquisition of Sentinelle Medical in the fourth quarter of fiscal 2010.

Diagnostics product sales increased 1% in fiscal 2010 compared to fiscal 2009 primarily due to an increase in sales of our Cervista HPV tests, and to a lesser extent other molecular tests. Partially offsetting these increases

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was a decrease in ThinPrep pap test volume domestically due to the decline in doctor visits, which we believe is attributable to the lagging effects of unemployment, continuing economic uncertainty and recent changes in cervical cancer screening guidelines to extend the recommended intervals between such screenings, and the discontinuance of certain molecular ASRs, which contributed $3.5 million of revenue in 2009. In addition, we have seen laboratory consolidation, which impacts our average selling prices due to volume purchase discounts to the larger laboratories.

GYN Surgical product sales increased 7% in fiscal 2010 compared to fiscal 2009 primarily due to growing sales of the Adiana system, which was approved by the FDA in the fourth quarter of fiscal 2009, and to a lesser extent, an increase in the number of NovaSure products sold. We also experienced a slight increase in the NovaSure system average selling prices.

Skeletal Health product sales decreased 11% in fiscal 2010 compared to fiscal 2009 primarily due to a decrease in mini C-arms sales of $4.6 million as a result of a reduction in the number of units sold. In addition, there was a $3.6 million decrease in osteoporosis assessment product sales principally due to a decrease in the number of bone densitometry systems sold worldwide. This product line has experienced a difficult capital equipment environment worldwide and the ongoing effects of the reduction in reimbursement for osteoporosis exams in the U.S.

In fiscal 2010, approximately 79% of product sales were generated in the United States, 12% in Europe, 5% in Asia, and 4% in other international markets. In fiscal 2009, approximately 80% of product sales were generated in the United States, 12% in Europe, 4% in Asia, and 4% in other international markets.

Service and Other Revenues.

	Years Ended					
	September 25, 2010		September 26, 2009		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Service and Other Revenues	$ 264,652	16%	$ 210,148	13%	$ 54,504	26%

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. Service and other revenues increased 26% in fiscal 2010 compared to fiscal 2009 primarily in our Breast Health business due to an increase in the number of service contracts driven by an increase in our installed base of our full field digital mammography systems.

Cost of Product Sales.

	Years Ended					
	September 25, 2010		September 26, 2009		Change	
	Amount	% of Product Sales	Amount	% of Product Sales	Amount	%
Cost of Product Sales	$ 487,057	34%	$ 463,066	33%	$ 23,991	5%
Cost of Product Sales Amortization of Intangible Assets	171,447	12%	155,519	11%	15,928	10%

Cost of Product Sales Impairment of Intangible Assets	123,350	9%	4,065	0%	119,285	2,934%
	$ 781,854	55%	$ 622,650	44%	$ 159,204	26%

Product sales gross margin decreased to 45% in fiscal 2010 compared to 56% in fiscal 2009 primarily due to the significant intangible asset impairment charge of $123.4 million recorded in fiscal 2010.

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Cost of Product Sales. The cost of product sales as a percentage of product sales in fiscal 2010 was 34% compared to 33% in fiscal 2009. Cost of product sales as a percentage of product revenues increased across our business segments, except Skeletal Health which remained relatively flat with the prior year. The decline in gross margin in fiscal 2010 was driven by a shift in product mix of our Selenia digital mammography systems to lower margin configurations, a higher level of international sales, and a slight reduction in average selling prices in our Breast Health segment. In addition, we experienced unfavorable manufacturing variances related to our Adiana System and lower absorption of manufacturing costs.

Cost of Product Sales Amortization of Intangible Assets. Amortization of intangible assets relates to acquired developed technology. The increase in amortization in fiscal 2010 was due to the method of recognition based on the expected economic benefits of the underlying assets, and was primarily related to the intangible assets acquired in the Cytyc merger in the first quarter of fiscal 2008.

Cost of Product Sales Impairment of Intangible Assets. During the fourth quarter of fiscal 2010 in connection with our Company-wide annual budgeting and strategic planning process, we determined that indicators of impairment existed in our MammoSite reporting unit due to changing market conditions for the breast brachytherapy market, including downward pressure on procedure volumes due to the continuing adverse macroeconomic environment and current trends in breast cancer management, as well as competitive pricing pressures and competition from existing and alternative new technologies. These factors resulted in lowering our financial projections for MammoSite. We performed the first step in the long-lived assets impairment test and compared MammoSite s forecasted undiscounted cash flows to the carrying value of its net assets, which indicated that these cash flows were insufficient to recover MammoSite s carrying value. Therefore, we determined the fair value of MammoSite s long-lived assets, which were primarily intangible assets, using a discounted cash flow technique. Based on the fair value of the long-lived assets, we recorded an impairment charge of $123.4 million to developed technology in the fourth quarter of fiscal 2010. During the second quarter of fiscal 2009, we decided to discontinue selling a certain product acquired in the Third Wave acquisition, which was an indicator of impairment, and therefore, we performed an impairment test. Due to the insufficient cash flows to be generated, we determined that the related asset group s fair value was de minimus and recorded an impairment charge of $4.1 million comprised of developed technology of $2.6 million and capitalized license fees of $1.5 million.

Cost of Service and Other Revenues.

	Years Ended					
	September 25, 2010		September 26, 2009		Change	
	Amount	% of Service and Other Revenues	Amount	% of Service and Other Revenues	Amount	%
Cost of Service and Other Revenues	$ 161,060	61%	$ 156,998	75%	$ 4,062	3%

Service and other revenues gross margin improved to 39% in fiscal 2010 from 25% in fiscal 2009 due in part to the improved absorption of fixed service costs as a result of the continued growth of service contract revenue, primarily in the Breast Health business. We have been able to convert a high percentage of our domestic installed base of full field digital mammography systems to service contracts upon the expiration of the warranty period.

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Operating Expenses.

	Years Ended September 25, 2010		September 26, 2009		Change	
	Amount	% of Total Revenue	Amount	% of Total Revenue	Amount	%
Operating Expenses						
Research and development	$ 104,305	6%	$ 102,453	6%	$ 1,852	2%
Selling and marketing	247,374	15%	238,977	15%	8,397	4%
General and administrative	148,340	9%	140,700	9%	7,640	5%
Amortization of intangible assets	54,858	3%	51,210	3%	3,648	7%
Impairment of goodwill	76,723	5%	2,340,023	143%	(2,263,300)	(97)%
Impairment of intangible assets	20,117	1%			20,117	100%
Litigation settlement charges, net	11,403	1%			11,403	100%
Acquired in-process research and development	2,000	0%			2,000	100%
Restructuring and divestiture charges, net	1,581	0%	797	0%	784	98%
	$ 666,701	40%	$ 2,874,160	176%	$ (2,207,459)	(77)%

Research and Development Expenses. Research and development expenses increased 2% in fiscal 2010 compared to fiscal 2009 due to an increase in clinical trial costs, primarily related to our tomosynthesis product, the addition of expenses from Sentinelle Medical since August 5, 2010 (the acquisition date), compensation and benefits, and engineering programs for a number of projects for product enhancements and new products. These increases were offset in part by a reduction of pre-release production costs that were incurred in fiscal 2009 related to the Adiana System that are no longer being incurred due to its FDA approval and commercial release in the fourth quarter of fiscal 2009.

Selling and Marketing Expenses. Selling and marketing expenses increased 4% in fiscal 2010 compared to fiscal 2009 primarily due to higher distributor and third-party commissions, additional expenses related to recently released products, trade shows and website marketing partially offset by lower compensation and expenditures for advertising and medical education.

General and Administrative Expenses. General and administrative expenses increased 5% primarily due to higher legal fees related to increased litigation related activities, principally the Ethicon and SenoRx lawsuits, and higher employee compensation and benefits principally due to a transition payment to the former CEO of $1.7 million in the first quarter of fiscal 2010 and related continuing retention compensation, an increase in the value of our DCP, and increased bonuses, offset slightly by lower costs from the departure of certain employees that were not replaced. In addition, transaction costs related to acquisitions are now recorded as an expense and not capitalized as part of the purchase price, increasing general and administrative expenses in fiscal 2010. The increase in general and administrative expenses was partially offset by lower fees for accounting, tax and other consulting services, lower bad debt expense, and lower charges for the write-off of certain corporate-related fixed assets in fiscal 2010.

Amortization of Intangible Assets. Amortization of intangible assets results from customer relationships and trade names related to our acquisitions. These intangible assets are generally being amortized over their estimated useful lives of between 2 and 30 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed.

Impairment of Goodwill. During the fourth quarter of fiscal 2010, in connection with performing our Company-wide annual budgeting and forecasting process, we determined that indicators of impairment existed in

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our MammoSite reporting unit and recorded intangible asset impairment charges. The fair value of this reporting unit declined from fiscal 2009 primarily due to our reassessment of the overall market size of breast brachytherapy and a reduction in long-term growth projections. After determining the fair values of MammoSite s long-lived assets, other than goodwill, and writing these assets down to their fair values, we performed the 2-step goodwill impairment test for MammoSite. As a result of this analysis, we recorded a $76.7 million goodwill impairment charge. No other reporting units were deemed to be impaired in fiscal 2010. During the first quarter of fiscal 2009, based upon a combination of factors, including the deteriorating macro-economic environment, declines in the stock market and the decline of our market capitalization significantly below the book value of our net assets, we concluded that potential goodwill impairment indicators existed as of December 27, 2008. As a result, we performed an interim goodwill impairment analysis as of December 27, 2008. Step 1 of the impairment analysis indicated that the carrying value of the net assets of certain of our reporting units, acquired in connection with the Cytyc acquisition, exceeded the estimated fair value of those reporting units. As a result, we were required to complete Step 2 of the impairment analysis to determine the amount, if any, of goodwill impairment charges. We completed Step 2 of this analysis during the second quarter of fiscal 2009 and recorded a goodwill impairment charge of $2.34 billion in the three month period ended March 28, 2009. Refer to Note 2 Intangible Assets and Goodwill contained in Item 15 of this Annual Report for more information.

Impairment of Intangible Assets. As noted above under Cost of Product Sales Impairment of Intangible Assets, we determined that the long-lived assets in the MammoSite reporting unit were impaired. As a result of this analysis, we recorded a $20.1 million charge to write down customer relationships and trade name intangible assets to their fair values. Refer to Note 2 Intangible Assets and Goodwill contained in Item 15 of this Annual Report for more information.

Litigation Settlement Charges, Net. These charges are primarily comprised of our litigation with Ethicon Endo-Surgery, Inc. We had been engaged in litigation in which Ethicon had alleged patent infringement by our ATEC biopsy system of certain of their patents, and Ethicon had made similar claims of our Eviva biopsy system. On February 17, 2010, we entered into a settlement agreement with Ethicon, and all outstanding litigation between the parties was dismissed. In connection with the settlement agreement, we agreed to make a one-time payment to Ethicon of $12.5 million and ongoing royalties for sales of our ATEC and Eviva products, and Ethicon agreed to pay us ongoing royalties for sales of its Mammotome magnetic resonance imaging product.

Acquired In-Process Research and Development Expenses. During the fourth quarter of fiscal 2010, we acquired certain assets that were determined to have no future alternative use and recorded a $2.0 million charge within our Diagnostics segment.

Restructuring and Divestiture Charges. During the fourth quarter of fiscal 2010, we terminated the employment of certain employees in connection with completing the Sentinelle Medical acquisition and recorded severance and related benefit costs of $0.9 million. The terminations occurred prior to September 25, 2010. During the second quarter of fiscal 2010, we completed the sale of the capital stock of our organic photoconductor drum coating manufacturing operation in Shanghai, China for a net sales price of $3.8 million resulting in a loss on disposal of $0.3 million. During the fourth quarter of 2009, we closed this manufacturing operation due to Chinese government requirements to move the facility. In connection with this action, we recorded restructuring costs for severance benefits and other costs of $0.8 million in the fourth quarter of fiscal 2009. In fiscal 2010, we incurred clean-up and closure costs of $0.4 million, net.

Interest Income.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Interest Income	$ 1,278	$ 1,161	$ 117	10%

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Interest income increased in fiscal 2010 compared to fiscal 2009 primarily due to an increase in invested balances partially offset by a decline in interest rates.

Interest Expense.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Interest Expense	$ (127,107)	$ (134,957)	$ (7,850)	(6)%

Interest expense consists primarily of the interest costs and the related amortization of the debt discount of our 2.00% Convertible Notes as well as the amortization of deferred financing costs. In fiscal 2010, we adopted a new accounting standard, FASB Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1) (codified within Accounting Standards Codification 470, *Debt*), that changed the accounting for convertible debt instruments with cash settlement features and required us to allocate a portion of our Convertible Notes to equity based on the relative fair value of the embedded conversion feature in our Convertible Notes. This component is recorded as a debt discount and is amortized to interest expense. This new accounting standard was retrospectively applied to prior periods (see Note 5(a) contained in Item 15 of this Annual Report for additional information). In addition, we incurred interest costs and the related amortization of deferred financing costs of our senior secured credit agreement. Interest expense decreased in fiscal 2010 compared to fiscal 2009 primarily due to paying down the outstanding principal amounts under our senior secured credit agreement, which were fully paid off in the third quarter of this year, partially offset by higher overall interest expense on our Convertible Notes due to using the effective interest method to amortize the debt discount.

Other Income (Expense), net.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Other Income (Expense), net	$ 901	$ (3,660)	$ 4,561	125%

In fiscal 2010, this account was primarily comprised of an increase in the cash surrender value of life insurance contracts related to our DCP of $1.3 million, which is driven by changes in stock market valuation, an increase related to non-income tax related government credits of $0.8 million partially offset by the write-off of a cost-method investment of $1.1 million due to an other-than-temporary impairment charge. In fiscal 2009, this account was primarily comprised of other-than-temporary impairment charges of cost-method investments of $2.2 million and foreign currency transaction losses of $2.3 million, offset by a $0.7 million increase in the cash surrender value of life insurance contracts related to our DCP.

Provision for Income Taxes.

	Years Ended		
	September 25, 2010	September 26, 2009	Change

	Amount	Amount	Amount	%
Provision for Income Taxes	$ 7,822	$ 62,512	$ (54,690)	(87)%

Our effective tax rate for fiscal 2010 was 14.2% of the pre-tax loss compared to 2.9% of the pre-tax loss in fiscal 2009. Our effective tax rate for fiscal 2010 was significantly impacted by the $76.7 million goodwill impairment charge recorded in the fourth quarter, substantially all of which was not deductible for tax purposes.

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The effective tax rate for fiscal 2009 was significantly impacted by the $2.34 billion goodwill impairment charge recorded in the second quarter of fiscal 2009, substantially all of which was not deductible for tax purposes.

Segment Results of Operations

The discussion that follows is a summary analysis of total revenues and the primary changes in operating income or loss by segment.

Breast Health.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 755,542	$ 728,884	$ 26,658	4%
Operating Loss	$ (93,623)	$ (122,559)	$ 28,936	24%
Operating Loss as a % of Segment Revenue	(12)%	(17)%		

Breast Health revenues increased in fiscal 2010 compared to fiscal 2009 primarily due to a $54.1 million increase in service revenues that is substantially related to additional service contracts for the increased number of Selenia systems in our installed base partially offset by the decrease in product revenues of $27.4 million discussed above.

The operating loss for this business segment decreased in fiscal 2010 compared to fiscal 2009 primarily due to a $220.2 million intangible asset and goodwill impairment charge related to our MammoSite reporting unit recorded in the fourth quarter of fiscal 2010 as compared to the $265.9 million goodwill impairment charge related to our MammoSite reporting unit recorded in the second quarter of fiscal 2009. Excluding the impact of these goodwill and intangible asset impairment charges, operating income decreased $16.8 million in fiscal 2010 compared to fiscal 2009 primarily due to the $12.5 million litigation settlement charge recorded in the second quarter of fiscal 2010 for the settlement of the Ethicon matter discussed above. Overall, our gross margins declined significantly to 31% due to the intangible asset impairment charge to write down developed technology related to our MammoSite reporting unit. Excluding this impairment, gross margins were relatively flat at 47% in both fiscal 2010 and 2009. Gross margin was positively impacted by an improved service revenues gross margin as a result of our relatively fixed cost structure to support service contracts, which was partially offset by a reduction in product gross margin to 54% from 58% in fiscal 2009 primarily due to a shift in product mix of our Selenia digital mammography systems to lower margin configurations, a higher level of international sales, and slight pressure on average selling prices. In addition, the increase in service revenues, which have lower gross margins than product sales, resulted in overall lower gross margins. The fiscal 2010 operating loss included higher clinical trial expenses principally related to clinical trials for our tomosynthesis product, increased litigation costs and higher third-party commissions compared to fiscal 2009. Fiscal 2010 also included Sentinelle Medical operating expenses and acquisition related transaction costs and charges aggregating approximately $5.0 million.

Diagnostics.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 552,501	$ 547,892	$ 4,609	1%
Operating Income (Loss)	$ 100,469	$ (809,640)	$ 910,109	112%
Operating Income (Loss) as a % of Segment Revenue	18%	(148)%		

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Diagnostics revenues increased in fiscal 2010 compared to fiscal 2009 primarily due to product sales discussed above.

Operating income for this business segment in fiscal 2010 increased compared to fiscal 2009 primarily due to a $908.3 million goodwill impairment charge and a $4.1 million intangible asset charge recorded in the second quarter of fiscal 2009. Excluding the impact of these charges, operating income was essentially flat in fiscal 2010 compared to fiscal 2009 due to lower operating expenses, which declined $7.5 million, partially offset by a reduction in gross margin to 53% from 55%. Gross margin declined primarily due to lower absorption of manufacturing costs as a result of lower volumes of ThinPrep, and higher intangible asset amortization expense. Gross margin in fiscal 2009 included a $4.1 million intangible asset charge. Operating expenses declined primarily due to lower legal expenses, lower employee compensation and benefits as a result of the departure of certain senior personnel. Operating expenses in fiscal 2010 included an acquired in-process research and development charge of $2.0 million for the acquisition of certain assets which had no future alternative use.

GYN Surgical.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 283,142	$ 264,900	$ 18,242	7%
Operating Income (Loss)	$ 53,071	$ (1,097,685)	$ 1,150,756	105%
Operating Income (Loss) as a % of Segment Revenue	19%	(414)%		

GYN Surgical revenues increased in fiscal 2010 compared to fiscal 2009 primarily due to the increase in product sales discussed above.

The operating loss in this segment in fiscal 2009 included a $1.17 billion goodwill impairment charge recorded in the second quarter of fiscal 2009. Excluding the impact of the goodwill impairment charge, operating income in fiscal 2010 decreased $15.1 million compared to fiscal 2009 due to a reduction in gross margin to 61% from 67% and higher operating expenses of $10.6 million compared to the corresponding period in the prior year. The decrease in gross margin is primarily due to unfavorable manufacturing variances related to the Adiana System, higher manufacturing and material costs related to our next generation NovaSure product and higher intangible asset amortization expense. Operating expenses increased primarily due to higher compensation costs for sales and marketing personnel as a result of an increase in headcount, higher commissions driven by an increase in revenues, and higher intangible asset amortization expense. In addition, we had higher Adiana System product launch activities as FDA approval was received in the fourth quarter of fiscal 2009.

Skeletal Health.

	Years Ended			
	September 25, 2010	September 26, 2009	Change	
	Amount	Amount	Amount	%
Total Revenues	$ 88,367	$ 95,458	$ (7,091)	(7)%
Operating Income	$ 10,020	$ 13,210	$ (3,190)	(24)%

Operating Income as a % of Segment Revenue	11%	14%

Skeletal Health revenues decreased in fiscal 2010 compared to fiscal 2009 primarily due to the decline in product sales discussed above.

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Operating income for this business segment decreased primarily due to lower sales and higher operating expenses. Gross margin in fiscal 2010 was relatively flat at 42% compared to 41% in fiscal 2009.

LIQUIDITY AND CAPITAL RESOURCES

At September 24, 2011, we had $833.5 million of working capital, and our cash and cash equivalents totaled $712.3 million. Our cash and cash equivalents balance increased by $196.7 million during fiscal 2011 due to cash generated from our operations partially offset by cash used in investing activities primarily for the purchase of Interlace, TCT and Healthcome, capital expenditures and placement of equipment under customer usage agreements, and the payment of contingent consideration.

Our operating activities provided us with $456.0 million of cash, which included net income of $157.2 million increased by non-cash charges for depreciation and amortization of an aggregate $304.7 million, non-cash interest expense of $76.8 million related to our convertible notes, the loss on extinguishment of debt of $29.9 million related to the exchange of convertible notes, and stock-based compensation expense of $35.5 million. These adjustments to net income were partially offset by the gain on the sale of intellectual property, net, of $84.5 million, a decrease in net deferred tax liabilities of $48.1 million primarily the result of amortization of intangible assets, and $8.0 million to record fair value adjustments to contingent consideration related to recent acquisitions. Cash provided by operations included a net cash outflow of $13.2 million from changes in our operating assets and liabilities. Changes in our operating assets and liabilities were driven primarily by an increase in inventory of $32.2 million due to an increase in components on hand to support higher sales volume, the introduction of new products and last-time buys of certain components, an increase of accounts receivable of $17.1 million due to an increase in revenues in the fourth quarter of fiscal 2011 compared to the corresponding period in the prior year, and a $6.2 million increase in prepaid income taxes. Partially offsetting these uses of cash was an increase in accrued expenses of $40.6 million primarily due to compensation accruals and timing of payments.

During fiscal 2011, we used $266.6 million of cash in investing activities. This use of cash was primarily attributable to the purchase of Interlace, TCT and Healthcome aggregating net payments of $198.7 million, the payment of contingent consideration to the former shareholders of Adiana of $19.7 million and an aggregate of $55.7 million for the placement of equipment under customer usage agreements and purchases of property and equipment, which consisted primarily of manufacturing equipment and computer hardware. In addition, we also purchased $5.3 million of life insurance contracts to fund future payments under our DCP. Partially offsetting these cash outflows was $13.3 million of proceeds from the sale of intellectual property assets, primarily related to the finalization of the Makena sale to KV. We received $12.5 million from KV in the second quarter of fiscal 2011. For additional explanation of this arrangement, please refer to Note 4 to the consolidated financial statements contained in Item 15 of this Annual Report.

During fiscal 2011, our financing activities provided us with $7.7 million of cash. This increase in cash was primarily attributable to proceeds of $25.4 million from the exercise of stock options and issuance of shares under our employee stock purchase plan, partially offset by the payment of $10.4 million of employee-related taxes withheld for the net share settlement of vested restricted stock units, the payment of issuance costs of $5.3 million related to our $450 million Exchange Notes (discussed below) and contingent consideration of $4.3 million paid to the former shareholders of Sentinelle Medical. Under ASC 805, the payment of contingent consideration is treated as a financing activity to the extent of the amount recorded in purchase accounting.

Debt

We had total recorded debt outstanding of $1.49 billion at September 24, 2011, which is primarily comprised of our Convertible Notes (principal $1.725 billion).

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Convertible Notes.

Original Convertible Notes. On December 10, 2007, we issued and sold $1.725 billion, at par, of our 2.00% Convertible Senior Notes due 2037 (Original Notes). The net proceeds from the offering was approximately $1.69 billion, after deducting the underwriters discounts and estimated offering expenses and was used to repay a portion of our then outstanding senior secured indebtedness under our Credit Agreement. At September 24, 2011, the Original Notes are recorded at $1.49 billion, which is net of the unamortized debt discount attributed to the embedded conversion feature of the Original Notes in accordance with FSP APB 14-1. See Note 5(a) contained in Item 15 of this Annual Report for more information. On November 18, 2010, we entered into separate, privately-negotiated exchange agreements under which we retired $450.0 million in aggregate principal of our Original Notes for $450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037 (Exchange Notes). Following these transactions, $1.275 billion in principal amount of the Original Notes remain outstanding.

Holders may require us to repurchase the Original Notes on December 13, 2013, and on each of December 15, 2017, 2022, 2027 and 2032, or upon a fundamental change, as described in the First Supplemental Indenture, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest. We may redeem any of the Original Notes beginning December 18, 2013, by giving holders at least 30 days notice. We may redeem the Original Notes either in whole or in part at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest, including contingent interest and liquidated damages, if any, to, but excluding, the redemption date.

The Original Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on June 15 and December 15 of each year, beginning June 15, 2008, and ending on December 15, 2013 and will accrete principal from December 15, 2013 at a rate that provides holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing December 15, 2013, we will pay contingent interest during any six month interest period to the holders of Original Notes if the trading price , as defined, of the Original Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the Original Notes. The holders of the Original Notes may convert the Original Notes into shares of our common stock at a conversion price of approximately $38.60 per share, subject to adjustment, prior to the close of business on September 15, 2037, subject to prior redemption or repurchase of the Original Notes, under any of the following circumstances: (1) during any calendar quarter after the calendar quarter ending December 31, 2007 if the last reported sale price of our common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (3) if the Original Notes have been called for redemption; or (4) upon the occurrence of specified corporate events. None of these triggering events had occurred as of September 24, 2011.

In lieu of delivery of shares of our common stock in satisfaction of our obligation upon conversion of the Original Notes, we may elect to deliver cash or a combination of cash and shares of our common stock. If we elect to satisfy our conversion obligation solely in cash, we will deliver cash in an amount as provided in the indenture for the Original Notes. If we elect to satisfy our conversion obligation in a combination of cash and shares of our common stock, we will deliver up to a specified dollar amount of cash per $1,000 original principal amount of Original Notes, and will settle the remainder of our conversion obligation in shares of our common stock, in each case based on the daily conversion value calculated as provided in the indenture for the Original Notes. In addition, at any time on or prior to the 35th scheduled trading day prior to the maturity date of the Original Notes, we may make an irrevocable election to settle conversions of the Original Notes either solely in cash or in a combination of cash and shares of our common stock with a specified cash amount at least equal to the accreted principal amount of the Original Notes. This net share settlement election is in our sole discretion and does not require the consent of holders of the Original Notes. It is our current intent and policy to settle any conversion of the Original Notes as if we had elected to make the net share settlement election.

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

Exchange Convertible Notes. On November 18, 2010, pursuant to separate, privately-negotiated exchange agreements, we retired $450.0 million in aggregate principal of our Original Notes for $450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037 (Exchange Notes).

Holders may require us to repurchase the Exchange Notes on December 15, 2016, and on each of December 15, 2020, December 15, 2025, December 13, 2030 and December 14, 2035 or upon a fundamental change, as described in the Second Supplemental Indenture, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest. We may redeem any of the notes beginning December 19, 2016, by giving holders at least 30 days notice. We may redeem the Exchange Notes either in whole or in part at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest, including contingent interest and liquidated damages, if any, to, but excluding, the redemption date.

The Exchange Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on June 15 and December 15 of each year, beginning December 15, 2010, and ending on December 15, 2016 and will accrete principal from December 15, 2016 at a rate that provides holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing December 15, 2016, we will pay contingent interest during any six month interest period to the holders of Exchange Notes if the trading price , as defined, of the Exchange Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the Exchange Notes. The holders of the Exchange Notes may convert the Exchange Notes into shares of our common stock at a conversion price of approximately $23.03 per share, subject to adjustment, prior to the close of business on September 15, 2037, subject to prior redemption or repurchase of the Exchange Notes, under any of the following circumstances: (1) during any calendar quarter after the calendar quarter ending December 31, 2010 if the last reported sale price of our common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such day; (3) if the Exchange Notes have been called for redemption; or (4) upon the occurrence of specified corporate events. None of these triggering events had occurred as of September 24, 2011.

In lieu of delivery of shares of our common stock in satisfaction of our obligation upon conversion of the Exchange Notes, we may elect to deliver cash or a combination of cash and shares of our common stock. If we elect to satisfy our conversion obligation solely in cash, we will deliver cash in an amount as provided in the indenture for the Exchange Notes. If we elect to satisfy our conversion obligation in a combination of cash and shares of our common stock, we will deliver up to a specified dollar amount of cash per $1,000 original principal amount of Exchange Notes, and will settle the remainder of our conversion obligation in shares of our common stock, in each case based on the daily conversion value calculated as provided in the indenture for the Exchange Notes. In addition, at any time on or prior to the 35th scheduled trading day prior to the maturity date of the Exchange Notes, we may make an irrevocable election to settle conversions of the Exchange Notes either solely in cash or in a combination of cash and shares of our common stock with a specified cash amount at least equal to the accreted principal amount of the Exchange Notes. This net share settlement election is in our sole discretion and does not require the consent of holders of the Exchange Notes. It is our current intent and policy to settle any conversion of the Exchange Notes as if we had elected to make the net share settlement election.

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

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Contingent Earn-Out Payments.

In connection with our acquisitions, we have incurred the obligation to make contingent earnout payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period. 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 earnout obligations may include covenants to operate the businesses acquired in a manner that may not otherwise be most advantageous to us.

Our contingent consideration arrangements are recorded as either additional purchase price or compensation expense if continuing employment is required to receive such payments. Pursuant to ASC 805, contingent consideration that is deemed to be part of the purchase price is recorded as a liability based on the estimated fair value of the consideration the Company expects to pay to the former shareholders of the acquired business as of the acquisition date. This liability is remeasured each reporting period with the changes in fair value recorded through a separate line item within the Company s Consolidated Statements of Operations. Increases or decreases in the fair value of contingent consideration liabilities can result from changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. Contingent consideration arrangements from acquisitions completed prior to the adoption of ASC 805 (effective in fiscal 2010 for us) that are deemed to be part of the purchase price of the acquisition are not subject to the fair value measurement requirements of ASC 805 and are recorded as additional purchase price to goodwill.

We have an obligation to the former Adiana, Inc. shareholders to make contingent payments tied to the achievement of milestones. The contingent payments of up to $155.0 million are based on worldwide sales of the Adiana system in the first year following FDA approval and on annual incremental sales growth thereafter through December 31, 2012. FDA approval of the Adiana system occurred on July 6, 2009, and we began accruing contingent consideration in the fourth quarter of fiscal 2009 based on the defined percentage of worldwide sales of the product. Since this contingent consideration obligation arose from an acquisition prior to the adoption of ASC 805, the amounts accrued are recorded as additional purchase price to goodwill and the obligation is not remeasured each reporting period through the statement of operations. The agreement includes an indemnification provision that provides for the reimbursement of qualifying legal expenses and liabilities associated with legal claims against the Adiana products and intellectual property, and we have the right to offset contingent consideration payments to the Adiana shareholders with these qualifying legal costs. We have been in litigation with Conceptus regarding certain intellectual property matters related to the Adiana product and are recording legal fees incurred for this litigation matter (described in Note 15 to the consolidated financial statements contained in Item 15 of this Annual Report) as a reduction to the accrued contingent consideration payments, which will result in a lower payment to the Adiana shareholders. We made a payment of $19.7 million to the Adiana shareholders in October 2010, net of amounts withheld for the legal indemnification provision. At September 24, 2011, the accrued contingent consideration obligation is $27.4 million, which is net of qualifying legal costs incurred. On October 17, 2011, the jury returned a verdict in the Conceptus litigation matter in favor of Conceptus and awarded damages in the amount of $18.8 million. This amount is included within, and may be offset against, the $27.4 million accrued as of September 24, 2011.

We also have contingent consideration obligations related to our Sentinelle Medical, Interlace, TCT and Healthcome acquisitions. Pursuant to ASC 805, contingent consideration pertaining to Sentinelle Medical and Interlace is required to be recorded as a liability at fair value and the adjustments to fair value are recorded in the Consolidated Statement of Operations. In connection with the Interlace acquisition, $2.1 million of the initial consideration was recorded as compensation expense and paid in fiscal 2011 based on continuing employment, and no further amounts of contingent consideration will be recorded as compensation expense related to this acquisition. Contingent consideration pertaining to TCT and Healthcome is contingent upon future employment and is being recorded as compensation expense as it is earned over the respective service periods. For additional information pertaining to the acquisitions, contingent consideration terms and the assumptions used to fair value contingent consideration, refer to Note 3 to the consolidated financial statements contained in Item 15 of this Annual Report.

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A summary of amounts recorded to the Consolidated Statement of Operations in fiscal 2011 is as follows:

Statement of Operations Line Item	Sentinelle Medical	Interlace	TCT	Healthcome	Total
Contingent consideration compensation expense	$	$ 2,102	$ 17,581	$ 319	$ 20,002
Contingent consideration fair value adjustments	(14,328)	6,312			(8,016)
	$ (14,328)	$ 8,414	$ 17,581	$ 319	$ 11,986

In connection with our acquisition of Sentinelle Medical, we have an obligation to the former stockholders to make contingent payments over a two-year period of up to a maximum of $250.0 million based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition. We made the first payment of $4.3 million in the third quarter of fiscal 2011, and at September 24, 2011, this liability is recorded at $10.9 million.

In connection with our acquisition of Interlace, we have an obligation to the former stockholders to make contingent payments over a two-year period up to a maximum payout of $225.0 million based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition. No amounts have been paid, and at September 24, 2011, this liability is recorded at $92.9 million.

Under the sale and purchase agreement for TCT, $35.0 million of the purchase price is deferred for one year from the date of the acquisition, and any working capital adjustment, which is currently estimated to be $13.0 million (collectively, the Deferred Installment Payment) is due with the $35.0 million. In addition, we have an obligation to certain of the former shareholders, based on future employment, to make contingent payments over a two year period not to exceed $200.0 million less the Deferred Installment Payment. Each of the components of the purchase price, as well as thresholds, are subject to adjustment. At September 24, 2011, we have accrued $17.6 million for these contingent payments.

In connection with our acquisition of Healthcome, we have an obligation to the former shareholders, who remain employed, to make contingent payments up to $7.1 million over three years. At September 24, 2011, we have accrued $0.3 million for these contingent payments.

A summary of amounts recorded in the Consolidated Balance Sheet at September 24, 2011 is as follows:

	Adiana	Sentinelle Medical	Interlace	TCT	Healthcome	Total
Accrued contingent consideration	$ 27,437	$ 10,878	$ 92,912	$ 17,581	$ 319	$ 149,127

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Contractual Obligations

The following table summarizes our contractual obligations and commitments as of September 24, 2011:

	Payments Due by Period				
Contractual Obligations	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**	**Total**
Long-Term Debt Obligations (1)	$	$ 1,275,000	$	$ 450,000	$ 1,725,000
Interest on Long-Term Debt Obligations	34,500	56,250	18,000	4,500	113,250
Operating Leases	19,793	31,703	19,863	33,461	104,820
Financing Leases (2)	2,598	5,585	5,937	6,346	20,466
Accrued Contingent Consideration (3)	100,255	48,872			149,127
Deferred payment to TCT	47,949				47,949
Purchase Obligations (4)	27,678	6,205	144		34,027
Pension Obligations (5)	349	760	835	6,120	8,064
Private Equity Investment (6)	524				524
Total Contractual Obligations	$ 233,646	$ 1,424,375	$ 44,779	$ 500,427	$ 2,203,227

(1) Our Convertible Notes can first be put to us on December 13, 2013, and we have assumed for purpose of the above table that the remaining portion of the Original Notes will be paid off in fiscal 2014. On November 18, 2010, we exchanged Exchange Notes in an aggregate principal amount of $450.0 million for Original Notes in the aggregate principal amount of $450.0 million. The first put date on the Exchange Notes is December 15, 2016, and we have assumed for purposes of the above table that the Exchange Notes will be paid off in fiscal 2017.

(2) The financing leases represent two leases for an office building and a manufacturing facility, which were required to be recorded on our balance sheet under US GAAP. See Note 12 to our consolidated financial statements contained in Item 15 of this Annual Report for more information.

(3) Amounts represent those recorded in accrued expenses and other long-term liabilities on our consolidated balance sheet. See Contingent Earn-Out Payments for a more complete description of our contingent earn-out obligations.

(4) Purchase obligations primarily relate to inventory purchases, and to a lesser extent, other operating expense commitments.

(5) Pension obligations do not include our obligation under the DCP of $17.2 million, which is recorded as a current liability. The DCP benefits are generally paid out at retirement or termination of employment.

(6) This represents a private equity investment commitment with a limited liability partnership.

The above table does not reflect our long-term liabilities associated with uncertain tax positions recorded under FIN 48 (codified primarily in ASC 740, *Income Taxes*) totaling $11.2 million. Due to the complexity associated with tax uncertainties, we cannot reasonably make a reliable estimate of the period in which we expect to settle these non-current liabilities. See Note 8 to our consolidated financial statements contained in Item 15 of this Annual Report for more information on our unrecognized tax benefits. In addition, certain of our cost method equity investments give us the option to acquire the company in the future. Since it is not possible to estimate when, or even if, we will exercise our option to acquire these companies, we have not included these future potential payments in the table above.

Future Liquidity Considerations

We expect to continue to review and evaluate potential acquisitions of businesses, products or technologies, and strategic alliances that we believe will complement our current or future business. Subject to the Risk Factors set forth in Part I, Item 1A of this Annual Report and the general disclaimers set forth in our Special Note Regarding Forward-Looking Statements at the outset of this Annual Report, we believe that cash flow from

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operations will provide us with sufficient funds in order to fund our expected operations over the next twelve months. Our longer-term liquidity is contingent upon future operating performance. We may also require additional capital in the future to fund capital expenditures, contingent consideration obligations, acquisitions or other investments, or to repay our convertible notes and related deferred tax liabilities. The holders of the Original Notes in the principal amount of $1.275 billion may require us to repurchase the notes on December 13, 2013, and on each of December 15, 2017, 2022, 2027 and 2032 at a repurchase price equal to 100% of their accreted principal amount, and the holders of the Exchange Notes in the principal amount of $450.0 million may require us to repurchase the notes on December 15, 2016, December 15, 2020, December 15, 2025, December 13, 2030 and December 14, 2035. These capital requirements could be substantial. Our operating performance may also be affected by matters discussed under the above-referenced Risk Factors as elsewhere in this report. These risks, trends and uncertainties may also adversely affect our long-term liquidity.

Legal Contingencies

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

Inventory

Our inventories include material, labor and overhead, and are stated at the lower of cost (first-in, first-out) or market. As a developer and manufacturer of high technology medical equipment, we may be exposed to a number of economic and industry factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. These factors include, but are not limited to, technological

changes in our markets, our ability to meet changing customer requirements, competitive pressures on products and prices, reliability and replacement of and the availability of key components from our suppliers. Our policy is to establish inventory reserves when conditions exist that suggest that our inventory may be in excess of anticipated demand or is obsolete based upon our assumptions about future demand for our products and market conditions.

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We regularly evaluate our ability to realize the value of our inventory based on a combination of factors including the following: historical usage rates, forecasted sales or usage, product expiration or end of life dates, estimated current and future market values and new product introductions. Assumptions used in determining our estimates of future product demand may prove to be incorrect, in which case the provision required for excess and obsolete inventory would have to be adjusted in the future. If inventory is determined to be overvalued, we would be required to record impairment charges within cost of goods sold at the time of such determination. Although considerable effort is made to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant negative impact on the value of our inventory and our operating results. When recorded, our reserves are intended to reduce the carrying value of our inventory to its net realizable value.

Provisions for excess or obsolete inventory are primarily based on our estimates of forecasted net sales and service usage levels. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional provisions for excess or expired inventory in the future. We record provisions for excess or obsolete inventory as cost of product revenue.

Accounts Receivable Reserves

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We regularly evaluate the collectability of our trade receivables based on a combination of factors, including a dialogue with the customer to determine the cause of non-payment, and evaluation of the customer s current financial situation. In the event it is determined that the customer may not be able to meet its full obligation to us, we record a specific allowance to reduce the receivable to the amount that we expect to recover given all information present. We perform ongoing credit evaluations of our customers and adjust credit limits based upon payment history and our assessment of the customer s current credit worthiness. We continuously monitor collections from our customers and maintain a provision for estimated credit losses based upon our historical experience and any specific customer collection issues that we have identified. While such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates in the future. If the financial condition of our customers were to deteriorate, for example as a result of the ongoing financial and economic uncertainty or otherwise, resulting in an impairment of their ability to make payments, additional allowances may be required.

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

Business Combinations

We record tangible and intangible assets acquired and liabilities assumed in business combinations under the purchase method of accounting. Amounts paid for each acquisition are allocated to the assets acquired and liabilities assumed based on their fair values at the dates of acquisition. As a result of our adoption of ASC 805 in fiscal 2010, contingent consideration, which is not deemed to be linked to continuing employment, is recorded at fair value as measured on the date of acquisition. The value recorded is based on estimates of future financial projections under various potential scenarios, which are probability weighted as to the outcome of each scenario. These cash flow projections are discounted with an appropriate risk adjusted rate. Quarterly until such contingent amounts are earned, the fair value of the liability is reassessed at each reporting period and adjusted as a component of operating expenses based on changes to the underlying assumptions. The estimates used to determine the fair value of the contingent consideration liability are subject to significant judgment and actual results are likely to differ from the amounts originally recorded.

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The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions provided by management. We allocate any excess purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed to goodwill. The valuation of purchased research and development represents the estimated fair value at the date of acquisition related to in-process projects. Our purchased research and development represents the value of in-process projects that have not yet reached technological feasibility and have no alternative future uses as of the date of acquisition. As a result of our adoption of ASC 805, we capitalize these assets and record them in our consolidated balance sheet. Under ASC 805, in-process research and development assets are evaluated for impairment similar to goodwill and once the project is complete, if at all, the asset is amortized over its remaining useful life. Prior to the adoption of ASC 805, we expensed the value attributable to these in-process projects at the time of acquisition. If the projects are not successful or completed in a timely manner, we may not realize the financial benefits expected for these projects or for the acquisitions as a whole and impairments may result.

We use the income approach to determine the fair values of our purchased research and development. This approach determines fair value by estimating the after-tax cash flows attributable to an in-process project over its useful life and then discounting these after-tax cash flows back to a present value. We base our revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology and expected product introductions by competitors. In arriving at the value of the in-process projects, we consider, among other factors, the in-process projects stage of completion, the complexity of the work completed as of the acquisition date, the costs already incurred, the projected costs to complete, the contribution of core technologies and other acquired assets, the expected introduction date and the estimated useful life of the technology. We base the discount rate used to arrive at a present value as of the date of acquisition on the time value of money and medical technology investment risk factors. We believe that the estimated purchased research and development amounts so determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the projects.

We have also used the income approach, as described above, to determine the estimated fair value of certain other identifiable intangible assets including developed technology, customer relationships and trade names. Developed technology represents patented and unpatented technology and know-how. Customer relationships represent established relationships with customers, which provide a ready channel for the sale of additional products and services. Trade names represent acquired company and product names. For business licenses, we use a combination of the lost profits method and replacement cost method to value such assets. Business licenses allow us to conduct business in a certain country, namely China.

Intangible Assets and Goodwill

Intangible Assets

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

During the fourth quarter of fiscal 2010, in connection with our company-wide annual budgeting and strategic planning process, we determined that indicators of impairment existed in our MammoSite reporting unit, which is included in the Breast Health reportable segment, due to

changing market conditions for the brachytherapy market, 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

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and competition from existing and alternative new technologies. These factors resulted in us lowering the financial projections for MammoSite. As a result, we performed the first step in the long-lived assets impairment test pursuant to ASC 360 and compared MammoSite s forecasted undiscounted cash flows to the carrying value of its net assets. These undiscounted cash flows were insufficient to recover MammoSite s carrying value. Therefore, we determined the fair value of MammoSite s long-lived assets, which are primarily intangible assets, using a discounted cash flow technique. The expected future cash flows are Level 3 inputs under ASC 820 and are those expected to be generated by the market participants, discounted at an appropriate risk-adjusted rate. Based on the fair value of the long-lived assets, we recorded an aggregate impairment charge of $143.5 million to write these intangible assets down to their fair value. The charge was comprised of $123.4 million related to developed technology, which was recorded in cost of product sales, $11.8 million related to customer relationships and $8.3 million related to trade names, which were recorded in impairment of intangible assets. In addition, the Company recorded a goodwill impairment charge of $76.7 million (see below for further discussion).

Goodwill

We test goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business, and an adverse action or assessment by a regulator. Our annual impairment test date is the first day of our fiscal fourth quarter.

In performing the test, we utilize the two-step approach prescribed under ASC 350. The first step requires a comparison of the reporting unit s carrying value to its fair value. We consider a number of factors to determine the fair value of a reporting unit, including an independent valuation to conduct this test. The valuation is based upon expected future discounted operating cash flows of the reporting unit as well as analysis of recent sales or offerings of similar companies. We base the discount rate on the weighted average cost of capital (WACC) of market participants. If the carrying value of a reporting unit exceeds its fair value, we will perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit s goodwill to its carrying value.

We conducted our fiscal 2011 annual impairment test on the first day of the fourth quarter. We utilized discounted cash flow (DCF) and market approaches to estimate the fair value of our reporting units as of June 26, 2011, and ultimately used the fair value determined by the DCF in making its impairment test conclusions. We believe we have used reasonable estimates and assumptions about future revenue, cost projections, cash flows, market multiples and discount rates. As a result of completing Step 1, all of the reporting units had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required. For illustrative purposes, had the fair value of each reporting unit been lower by 10%, each reporting unit would have still passed Step 1 of the goodwill impairment test.

We conducted our fiscal 2010 annual impairment test on the first day of the fourth quarter. We utilized DCF and market approaches to estimate the fair value of our reporting units as of June 27, 2010, and believe we used reasonable estimates and assumptions about future revenue, cost projections, cash flows and market multiples. As a result of completing Step 1, all of the Company s reporting units, except MammoSite, had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required for these reporting units. MammoSite s fair value has declined from fiscal 2009 primarily due to a reduction in its long-term growth rates. The changes in MammoSite s financial projections were a result of changing market conditions for the brachytherapy market, 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. The DCF calculation of fair value was positively impacted by a reduction in the discount rate to 11.0% from 12.5% used in the fiscal 2009 annual impairment test.

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We performed the Step 2 analysis for MammoSite, consistent with the procedures described above, and recorded a $76.7 million goodwill impairment charge. For illustrative purposes had the fair value of MammoSite been 10% lower, the charge would have been higher by $2.5 million. If the fair value of the Company s other reporting units had been lower by 10%, one reporting unit would have failed Step 1 requiring a Step 2 analysis. This reporting unit is in the Breast Health reportable segment and had a fair value at the annual impairment measurement date that exceeded its carrying value by 4% with goodwill of $256.5 million. The fair value of the reporting unit was determined by use of the DCF, and the key assumptions that drive the fair value in this model are the WACC, terminal values, growth rates, and the amount and timing of expected future cash flows. If the current economic environment were to deteriorate, this would likely result in a higher WACC because market participants would require a higher rate of return. In the DCF as the WACC increases, the fair value decreases. The other significant factor in the DCF is our projected financial information (i.e., amount and timing of expected future cash flows and growth rates) and if these assumptions were to be adversely impacted, this could result in a reduction of the fair value of this reporting unit. At September 25, 2010, for our other reporting units with goodwill aggregating $1.85 billion as of September 25, 2010, we believed that these reporting units were not at risk of failing Step 1 of the goodwill impairment test.

During the first quarter of fiscal 2009, based upon a combination of factors, including the deteriorating macro-economic environment, declines in the stock market and the decline of our market capitalization significantly below the book value of our net assets, we concluded that potential goodwill impairment indicators existed as of December 27, 2008. As a result, we performed an interim goodwill impairment analysis as of December 27, 2008. Step 1 of the impairment analysis indicated that the carrying value of the net assets of certain reporting units, acquired in connection with the Cytyc acquisition, exceeded the estimated fair value of those reporting units. As a result, we were required to perform Step 2 of the goodwill impairment test to determine the amount, if any, of goodwill impairment charges for each of the applicable reporting units. The Step 2 analysis required us to perform a hypothetical purchase price allocation for each of these reporting units to determine the implied fair value of goodwill and to compare the implied fair value of goodwill to the recorded amount of goodwill by reporting unit. Due to the complexities and time involved in preparing the Step 1 analysis, we had not commenced the Step 2 analysis as of February 5, 2009, the date we filed our Form 10-Q for the quarter ended December 27, 2008. As a result of the fact that we had not commenced the Step 2 analysis and the complexity of the analysis required to complete the Step 2 analysis, we were unable to determine that an impairment loss, in accordance with ASC 450, was both probable and reasonably estimable at December 27, 2008. We completed the Step 2 analysis during our second quarter of fiscal 2009, which resulted in an aggregate goodwill impairment charge of $2.34 billion. This impairment charge is comprised of $1.17 billion for GYN Surgical, $908.3 million for Diagnostics, and $265.9 million for Breast Health related to our MammoSite reporting unit acquired from Cytyc. We believe that our procedures and related assumptions for estimating the reporting units fair value are reasonable and consistent with the market conditions that existed at the time of the impairment test.

For illustrative purposes, had the fair values of each reporting unit for which we recorded goodwill impairment charges in the second quarter of fiscal 2009 been lower by 10% as of December 27, 2008, we would have recorded an additional impairment charge of $435.5 million. Based on our estimates as of December 27, 2008, the impact of reducing our fair value estimates for our other reporting units, for which we did not record any goodwill impairment charges, by 10% would have had no impact on the goodwill assessment for those reporting units.

We conducted our annual impairment test as of the first day of the fourth quarter of fiscal 2009. In order to complete the annual impairment test, we updated our interim impairment test results and performed detailed analyses estimating the fair value of most of our reporting units utilizing our fiscal 2010 forecast with updated long-term growth assumptions. For one reporting unit, we utilized the results of our interim impairment test. Pursuant to ASC 350-20-35-29, we concluded that it met the required criteria to use the estimated fair value determined from its interim impairment analysis for this reporting unit because 1) the composition of the assets and liabilities of this reporting unit had not changed significantly since the most recent fair value determination,

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2) the most recent fair value determination resulted in a fair value that exceeded the carrying value of the reporting unit by a substantial margin, and 3) management concluded, based on an analysis of current events that had occurred and circumstances that had changed since the most recent fair value determination, that it is remote that the current fair value of the reporting unit would not exceed their carrying amounts.

As a result of completing Step 1, all of our reporting units, except one, had a fair value exceeding their carrying value, and as such, Step 2 of the impairment test was not required for these reporting units. For the reporting unit that failed Step 1, we completed Step 2 and determined that an impairment charge was not required due to the fair value of the implied goodwill exceeding the carrying value of the reporting unit s goodwill. For illustrative purposes, had the fair value of this reporting unit at June 28, 2009 been lower by 10%, the Company still would not have recorded any impairment charge.

The estimate of fair value requires significant judgment. Any loss resulting from an impairment test would be reflected in operating income (loss) in our Consolidated Statements of Operations. The annual impairment testing process is subjective and requires judgment at many points throughout the analysis. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets not previously recorded.

Conceptus Litigation. We have ongoing litigation with Conceptus regarding potential patent infringement of a Conceptus patent by our Adiana system. In the first quarter of fiscal 2012, the jury returned a verdict in favor of Conceptus and awarded Conceptus $18.8 million in damages. Post trial motions will be filed addressing certain issues that could impact the ultimate outcome of this case. We also expect that Conceptus will seek to enjoin us from further sales of the Adiana system. A hearing on the post trial motions and injunctions request is scheduled for December 22, 2011. The jury verdict and any such determinations are subject to appeal by either party. If Conceptus is successful in upholding the verdict, we may be required to remove the Adiana system from the market. The jury verdict and subsequent litigation status may be an indicator of impairment for our GYN Surgical reporting unit. A reduction in the anticipated future cash flows of our GYN Surgical reporting unit could result in a material impairment charge that would have an adverse impact on our operating results. We will further evaluate this matter in the first quarter of fiscal 2012 and will perform an interim goodwill impairment analysis and a long-lived asset impairment analysis, if required.

Revenue Recognition

We generate revenue from the sale of products, primarily medical imaging systems and diagnostic and surgical disposable products, and related services, which are primarily support and maintenance services on our medical imaging systems.

In September 2009, the FASB ratified ASC Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13). ASU 2009-13 amends existing revenue recognition accounting standards that are currently within the scope of ASC, Subtopic 605-25, which is the revenue recognition standard for multiple-element arrangements. ASU 2009-13 provides for three significant changes to the existing multiple element revenue recognition guidance as follows:

1) Removed the requirement to have objective and reliable evidence of fair value for undelivered elements in an arrangement. This may result in more deliverables being treated as separate units of accounting.

2) Modified the manner in which the arrangement consideration is allocated to the separately identified deliverables. ASU 2009-13 requires an entity to allocate revenue in an arrangement using its best estimate of selling prices (ESP) of deliverables if a vendor does

not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE), if VSOE is not available. Each separate unit of accounting must have a selling price, which can be based on management s estimate when there is no other means (VSOE or TPE) to determine the selling price of that deliverable. The arrangement consideration is allocated based on the elements relative selling prices.

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3) Eliminated use of the residual method and requires an entity to allocate revenue using the relative selling price method, which results in the discount in the transaction being evenly allocated to the separate units of accounting.

In September 2009, the FASB ratified ASU No. 2009-14, *Certain Revenue Arrangements that Include Software Elements* (ASU 2009-14). ASU 2009-14 amends the existing revenue recognition accounting standards to remove tangible products that contain software components and non-software components that function together to deliver the product s essential functionality from the scope of industry specific software revenue recognition guidance.

As permitted, we elected to early adopt these new accounting standards at the beginning of our first quarter of fiscal 2010 on a prospective basis for transactions originating or materially modified on or after September 27, 2009. These accounting standards generally do not change the units of accounting for our revenue transactions, and most products and services qualify as separate units of accounting. The impact of adopting these new accounting standards was not material to our financial statements for the year ended September 25, 2010, and if they were applied in the same manner to fiscal 2009 would not have had a material impact to revenue recorded in fiscal 2009, or any of the interim periods therein.

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

Service revenues primarily consist of amounts recorded under service and maintenance contracts and repairs not covered under warranty, installation and training, and shipping and handling costs billed to customers. Service and maintenance contract revenues are recognized ratably over the term of the contract. Other service revenues are recognized as the services are performed.

We typically determine the selling price of our products and services based on VSOE and determine VSOE based on our normal pricing and discounting practices for the specific product or service when sold on a stand-alone basis. In determining VSOE, our policy requires a substantial majority of selling prices for a product or service to be within a reasonably narrow range. We also consider the class of customer, method of distribution, and the geographies into which our products and services are sold when determining VSOE. We typically have had VSOE for our products and services.

If VSOE cannot be established, which may occur in instances when a product or service has not been sold separately, stand-alone sales are too infrequent, or product pricing is not within a narrow range, we attempt to establish the selling price based on TPE. TPE is determined based on competitor prices for similar deliverables when sold separately.

When we cannot determine VSOE or TPE, we use ESP in the allocation of arrangement consideration. The objective of ESP is to determine the price at which we would typically transact a stand-alone sale of the product or service. ESP is determined by considering a number of factors including our pricing policies, internal costs and gross margin objectives, method of distribution, information gathered from experience in customer negotiations, market research and information, recent technological trends, competitive landscape and geographies.

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Some of our products have both software and non-software components that function together to deliver the product s essential functionality. Prior to the adoption of ASU 2009-14, we had determined that except for our CAD products and Dimensions 2D/3D full field digital mammography products (Dimensions), the software element in our other products was incidental in accordance with the software revenue recognition rules and were not within the scope of the software revenue recognition rules, ASC 985-605, *Software Revenue Recognition*. We had determined that given the significance of the software component s functionality to our CAD systems and Dimensions products, which are in the Breast Health segment, these products were within the scope of the software revenue recognition rules.

ASC 985-605 generally requires revenue earned on software arrangements involving multiple elements to be allocated to each element based on their relative VSOE of fair value. If VSOE does not exist for a delivered element, the residual method is applied in which the arrangement consideration is allocated to the undelivered elements based on VSOE with the remaining consideration recognized as revenue for the delivered elements. For multiple-element software arrangements where VSOE of fair value of Post-Contract Customer Support (PCS) has been established, we recognize revenue using the residual method at the time all other revenue recognition criteria have been met.

Upon the release of the Dimensions product in fiscal 2009, we completed an evaluation of the software component in accordance with the software revenue recognition rules. As a result, we had determined that the Dimensions product contained software that was more than incidental to the product as a whole and should be accounted for under the software revenue recognition rules.

In connection with the adoption of ASU 2009-14, we re-evaluated the appropriate revenue recognition treatment of our products and determined that the Dimensions products, which have both software and non-software components that function together to deliver the products essential functionality (i.e., it is a tangible product), are scoped out of ASC 985-605, however, our CAD products will continue to be subject to ASC 985-605. Dimensions transactions entered into prior to the first quarter of fiscal 2010 will continue to be accounted for under ASC 985-605.

Under customer usage agreements, we install certain equipment (for example, a ThinPrep Processor or a ThinPrep Imaging System) at customer sites and customers commit to purchasing minimum quantities of disposable products at a stated price (generally including a usage fee for the equipment) over a defined contract term, which is typically between three and five years. Revenue is recognized over the term of the customer usage agreement as disposable products are delivered. We also rent certain equipment to customers and revenue from rental agreements is recorded over the term of the rental agreements.

Stock-Based Compensation

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

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

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

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

The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. ASC 718, *Stock Compensation,* requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical forfeitures, we have determined a specific forfeiture rate for certain employee groups and have applied forfeiture rates ranging from 0% to 5% as of September 24, 2011 depending on the specific employee group. This analysis is re-evaluated periodically and the forfeiture rate is adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will only be for those awards that vest.

We recognized $35.5 million, $34.2 million and $32.9 million of stock-based compensation expense for employee equity awards in fiscal years 2011, 2010 and 2009, respectively. As of September 24, 2011, there was $30.8 million and $32.2 million of unrecognized compensation expense related to stock options and restricted stock units, respectively, that we expect to recognize over a weighted-average period of 3.0 years and 2.4 years, respectively.

Income Taxes

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

We have recognized net deferred tax liabilities of $917.8 million at September 24, 2011 and $882.8 million at September 25, 2010. The liabilities primarily relate to deferred taxes associated with our acquisitions and the debt discount and original issuance discount on our Convertible Notes. The tax assets relate primarily net operating loss carryforwards, accruals and reserves, stock-based compensation, and research credits. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of the net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period such determination was made.

We had gross unrecognized tax benefits, including interest, of $30.6 million as of September 24, 2011 and $33.5 million as of September 25, 2010. At September 24, 2011, $30.6 million represents the amount of unrecognized tax benefits that, if recognized, would result in a reduction of the Company s effective tax rate. In the next twelve months, it is reasonably possible that we will reduce our unrecognized tax benefits by $2.6 million due to expiration of statute of limitations and settlements with taxing authorities, all of which would reduce our effective tax rate.

In the ordinary course of global business, there are many transactions and calculations where the ultimate tax outcome is uncertain. Judgment is required in determining our worldwide income tax provision. In our opinion, we have made adequate provisions for income taxes for all years subject to audit. Although we believe our estimates are reasonable, no assurance can be given that the final tax outcome of these matters will not be different than that which is reflected in our historical income tax provisions and accruals. In the event our assumptions are incorrect, the differences could have a material impact on our income tax provision and operating results in the period in which such determination is made.

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Recent Accounting Pronouncements

Presentation of Comprehensive Income

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 is effective for us in our first quarter of fiscal 2013 and should be applied retrospectively. We are currently evaluating the impact of the adoption of ASU 2011-05 on our consolidated financial statements.

Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements

In May 2011, the FASB issued ASU No. 2011-04 *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 is effective for us in our second quarter of fiscal 2012 and should be applied prospectively. We are currently evaluating the impact of the adoption of ASU 2011-04 on our consolidated financial statements.

Business Combinations

In December 2010, the FASB issued ASU No. 2010-29, *Business Combinations (ASC Topic 805) Disclosure of Supplementary Pro Forma Information for Business Combinations*. ASU 2010-29 requires a public entity to disclose revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the prior year. It also requires a description of the nature and amount of material, nonrecurring adjustments directly attributable to the business combination included in the reported revenue and earnings. The new disclosure will be effective for our first quarter of fiscal 2012. The adoption of ASU 2010-29 will require additional disclosure in the event of a business combination but will not have a material impact on our consolidated financial statements.

Intangibles Goodwill and Other

In December 2010, the FASB issued ASU No. 2010-28, *Intangibles Goodwill and Other (ASC Topic 350)*. ASU 2010-28 modifies Step 1 of the goodwill impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. ASU 2010-28 is effective for us in fiscal 2012. We do not believe that ASU 2010-28 will have a material impact on our consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. ASU 2011-08 allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. ASU 2011-08 is effective for us beginning in fiscal 2013, although early adoption is permitted. We do not believe that ASU 2011-08 will have a material impact on our consolidated financial statements.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments. Financial instruments consist of cash equivalents, accounts receivable, cost-method equity investments, insurance contracts and related DCP liability, accounts payable and debt obligations. Except for our outstanding Convertible Notes, the fair value of these financial instruments approximates their carrying amount. As of September 24, 2011, we have $1.725 billion of principal of Convertible Notes outstanding, which are comprised of our Original Notes with a principal of $1.275 billion and our Exchange Notes with a principal of $450.0 million. The Convertible Notes are recorded net of the unamortized discount on our consolidated balance sheets. The fair value of our Original Notes and Exchange Notes as of September 24, 2011 was approximately $1.20 billion and $468.7 million, respectively.

Primary Market Risk Exposures. Our primary market risk exposure is in the areas of interest rate risk and foreign currency exchange rate risk. The return from cash and cash equivalents will vary as short-term interest rates change. A hypothetical 10% increase or decrease in interest rates, however, would not have a material adverse effect on our financial condition.

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

We conduct business worldwide and maintain sales and service offices outside the United States as well as manufacturing facilities in Germany, Costa Rica, Canada and China. The expenses of our international offices are denominated in local currencies, except at our Costa Rica subsidiary, where the majority of the business is conducted in U.S. dollars. Our international sales are denominated in a number of currencies, primarily the Euro and U.S. dollar. Fluctuations in the foreign currency rates could affect our sales, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluations can result in a loss if we hold deposits of that currency.

We believe that the operating expenses of our international subsidiaries that are incurred in local currencies will not have a material adverse effect on our business, results of operations or financial condition. Our operating results and certain assets and liabilities that are denominated in the Euro are affected by changes in the relative strength of the U.S. dollar against the Euro. Our expenses denominated in Euros are positively affected when the United States dollar strengthens against the Euro and adversely affected when the United States dollar weakens. However, we believe that the foreign currency exchange risk is not significant. A hypothetical 10% increase or decrease in foreign currencies that we transact in would not have a material adverse effect on our financial condition or results of operations. During fiscal 2011, 2010 and 2009, we incurred net foreign exchange losses of $0.7 million, $1.1 million and $2.3 million, respectively.

Item 8. Financial Statements and Supplementary Data.

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

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated

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to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of September 24, 2011, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Report of Management on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting as of September 24, 2011. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Management has excluded from our assessment of and conclusion on the effectiveness of internal control over financial reporting the internal controls of TCT International Co., Ltd. acquired in June 2011 and Beijing Healthcome Technology Company, Ltd. acquired in July 2011, which are included in the consolidated financial statements of Hologic, Inc. as of and for the year ended September 24, 2011 constituting $60.8 million

and $34.5 million of total and net assets, respectively, as of September 24, 2011, and $17.3 million and $0.4 million of revenues and net loss, respectively, for the year then ended.

Subject to the foregoing, based on management s assessment, we believe that, as of September 24, 2011, our internal control over financial reporting is effective at a reasonable assurance level based on these criteria.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting. This report in which they expressed an unqualified opinion is included below.

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Report of Independent Registered Public Accounting Firm

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

We have audited Hologic Inc. s (the Company) internal control over financial reporting as of September 24, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying Form 10-K, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of TCT International Co., Ltd. (TCT) acquired in June 2011 or Beijing Healthcome Technology Company, Ltd. (Healthcome) acquired in July 2011, which are included in the September 24, 2011 consolidated financial statements of Hologic, Inc. and constituted $60.8 million and $34.5 million of total and net assets for TCT and Healthcome, respectively, as of September 24, 2011 and $17.3 million and $0.4 million of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Hologic, Inc. also did not include an evaluation of the internal control over financial reporting of TCT International Co. Ltd. or Beijing Healthcome Technology Company, Ltd.

In our opinion, Hologic, Inc. maintained, in all material respects, effective internal control over financial reporting as of September 24, 2011, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Hologic, Inc. as of September 24, 2011 and September 25, 2010 and the related consolidated statements of operations, stockholders equity and other comprehensive loss and cash flows for each of the three years in the period ended September 24, 2011 of Hologic, Inc. and our report dated November 23, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

November 23, 2011

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Changes in Internal Control over Financial Reporting

During the quarter ended September 24, 2011, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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PART III

Item 10. Directors, and Executive Officers and Corporate Governance.

Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002, we have adopted a Code of Ethics for Senior Financial Officers that applies to our principal executive officer and principal financial officer, principal accounting officer and controller, and other persons performing similar functions. Our Code of Ethics for Senior Financial Officers is publicly available on our website at *www.hologic.com* under Investor Relations. We intend to satisfy the disclosure requirement under Item 5.05 of Current Report on Form 8-K regarding an amendment to, or waiver from, a provision of this code by posting such information on our website, at the address specified above.

The additional information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

We maintain a number of equity compensation plans for employees, officers, directors and others whose efforts contribute to our success. The table below sets forth certain information as of the end of our fiscal year ended September 24, 2011 regarding the shares of our common stock available for grant or granted under stock option plans and equity incentives that (i) were approved by our stockholders, and (ii) were not approved by our stockholders.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b) (2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	18,277,270	$ 17.26	8,245,251
	311,953	$ 4.60	

Equity compensation plans not approved by security holders (3)				
Total	18,589,223	$	17.01	8,245,251

(1) Includes 3,111,656 shares that are issuable upon RSUs vesting. The remaining balance consists of outstanding stock option grants.

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

(3) Includes the following plans: 1997 Employee Equity Incentive Plan and 2000 Acquisition Equity Incentive Plan. A description of each of these plans is as follows:

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1997 Employee Equity Incentive Plan. The purposes of the 1997 Employee Equity Incentive Plan (the 1997 Plan), adopted by the Board of Directors in May 1997, were to attract and retain key employees, consultants and advisors, to provide an incentive for them to assist us in achieving long-range performance goals, and to enable such person to participate in our long-term growth. In general, under the 1997 Plan, all employees, consultants, and advisors who were not executive officers or directors were eligible to participate in the 1997 Plan. The 1997 Plan is administered by our Compensation Committee. Participants in the 1997 Plan are eligible to receive non-qualified stock options, stock appreciation rights, restricted stock and performance shares. A total of 4,400,000 shares of our common stock were reserved for issuance under the 1997 Plan. Of the shares reserved for issuance under the 1997 Plan, options to purchase 199,303 shares are outstanding as of September 24, 2011. In September 2005, our Compensation Committee determined that no further awards would be made under this plan and cancelled all remaining 332,168 shares available for issuance under the 1997 Plan that were not subject to outstanding stock option awards.

2000 Acquisition Incentive Plan. The purpose of the 2000 Acquisition Equity Incentive Plan (the 2000 Plan), adopted by the Board of Directors in April 2001, was to attract and retain (a) employees, consultants and advisors, of newly acquired businesses who have been or were being hired as employees, consultants or advisors of our company or any of our consolidated subsidiaries, and (b) employees, consultants and advisors, of our company who have or were anticipated to provide significant assistance in connection with the acquisition of a newly acquired business or its integration with our company, and to provide such persons an incentive for them to achieve long-range performance goals, and to enable them to participate in our long-term growth. In general, under the 2000 Plan, only employees, consultants and advisors who were not officers or directors of our company were eligible to participate in the 2000 Plan. The 2000 Plan was administered by our Compensation Committee. Participants in the 2000 Plan were eligible to receive non-qualified stock options, stock appreciation rights, restricted stock and performance shares. A total of 3,200,000 shares of our common stock were reserved for issuance under the 2000 Plan. Of the shares reserved for issuance under the 2000 Plan, options to purchase 112,650 shares were outstanding as of September 24, 2011. In September 2005, our Compensation Committee determined that no further awards would be made under this plan and cancelled all remaining 835,408 shares, available for issuance under the 2000 Plan that were not subject to outstanding stock option awards.

The additional information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 13. Certain Relationships and Related Transactions.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

(1) Financial Statements

Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements

Consolidated Statements of Operations for the years ended September 24, 2011, September 25, 2010 and September 26, 2009

Consolidated Balance Sheets as of September 24, 2011 and September 25, 2010

Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) for the years ended September 24, 2011, September 25, 2010 and September 26, 2009

Consolidated Statements of Cash Flows for the years ended September 24, 2011, September 25, 2010 and September 26, 2009

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto.

(b) Listing of Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
2.1	Agreement and Plan of Merger, dated as of June 8, 2008, by and among Hologic, Thunder Tech Corp. and Third Wave Technologies, Inc.	8-K	06/09/2008
3.1	Certificate of Incorporation of Hologic.	S-1	01/24/1990
3.2	Amendment to Certificate of Incorporation of Hologic.	10-Q	03/30/1996
3.3	Certificate of Amendment to Certificate of Incorporation of Hologic.	10-K	09/24/2005
3.4	Certificate of Amendment to Certificate of Incorporation of Hologic.	8-K	10/22/2007
3.5	Certificate of Amendment to Certificate of Incorporation of Hologic.	8-K	03/11/2008
3.6	Third Amended and Restated By-laws of Hologic.	8-K	03/04/2011
3.7	Amended and Restated Certificate of Designations of Series A Junior Participating Preferred Stock of Hologic.	8-A	04/03/2008
4.1	Specimen Certificate for Shares of Hologic s Common Stock.	8-A	01/31/1990
4.2	Description of Capital Stock (Contained in Hologic s Certificate of Incorporation, as amended, filed as Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 hereto).		
4.3	Amended and Restated Rights Agreement dated April 2, 2008.	8-A	04/03/2008
4.4	Form of Rights Certificate.	8-K	09/26/2002
4.5	Indenture, dated as of December 10, 2007, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	12/10/2007

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
4.6	First Supplemental Indenture, dated December 10, 2007, by and between Wilmington Trust Company, as Trustee, and Hologic.	8-K	12/10/2007
4.7	Second Supplemental Indenture, dated November 23, 2010, by and between Wilmington Trust Company, as Trustee, and Hologic.	10-K	09/25/2010
10.01*	Second Amended and Restated 1999 Equity Incentive Plan.	10-Q	03/25/2006
10.02*	Amendment No. 1 to Second Amended and Restated 1999 Equity Incentive Plan.	S-8	10/23/2007
10.03*	Amendment No. 2 to Second Amended and Restated 1999 Equity Incentive Plan.	8-K	10/22/2007
10.04*	Amendment No. 3 to Second Amended and Restated 1999 Equity Incentive Plan.	8-K	12/12/2008
10.05	2000 Acquisition Equity Incentive Plan.	10-K	09/29/2001
10.06*	2008 Equity Incentive Plan.	8-K	03/11/2008
10.07*	Form of Employee Stock Option Award Agreement Under 2008 Equity Incentive Plan.	8-K	11/17/2008
10.08*	Form of Employee Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan.	8-K	11/17/2008
10.09*	Form of Special Retention Employee Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan.	10-Q	06/26/2010
10.10*	Form of Independent Director Stock Option Award Agreement Under 2008 Equity Incentive Plan.	8-K	12/12/2008
10.11*	Form of Independent Director Restricted Stock Unit Award Agreement Under 2008 Equity Incentive Plan.	8-K	12/12/2008
10.12*	Amended and Restated 2008 Employee Stock Purchase Plan.	10-K	09/26/2009
10.13*	Hologic 2011 Short-Term Incentive Plan.	8-K	12/17/2010
10.14*	Cytyc Corporation 1995 Stock Plan.	S-8	10/23/2007
10.15*	Cytyc Corporation 1995 Non-Employee Director Stock Option Plan.	S-8	10/23/2007
10.16*	Cytyc Corporation 1998 Stock Plan of Pro Duct Health, Inc.	S-8	10/23/2007
10.17*	Cytyc Corporation 2001 Non-Employee Director Stock Plan.	S-8	10/23/2007
10.18*	Cytyc Corporation 2004 Omnibus Stock Plan.	S-8	10/23/2007
10.19*	Form of Indemnification Agreement (as executed with each director of Hologic).	8-K	03/06/2009
10.20*	Nonqualified Deferred Compensation Plan (formerly known as Amended and Restated Supplemental Executive Retirement Plan).	10-Q	12/27/2008
10.21*	Rabbi Trust Agreement.	10-K	09/30/2006
10.22*	Form of Officer Severance Agreement including list of officers to whom provided.	10-Q	03/25/2006

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
10.23*	Transition Agreement dated November 5, 2009, by and between Hologic and John W. Cumming.	8-K	11/09/2009
10.24*	Transition Acknowledgement dated July 28, 2011, by and between Hologic and John W. Cumming.	8-K	08/01/2011
10.25*	Form of Senior Vice President Change of Control Agreement including list of officers to whom provided.	10-Q	12/27/2008
		10-K	09/25/2010
10.26*	Form of Senior Executive Officer Change of Control Agreement including list of officers to whom provided.	8-K	11/17/2009
10.27*	Second Retention Agreement with Robert A. Cascella dated as of October 22, 2007.	8-K	10/22/2007
10.28*	Restricted Stock Grant Agreement with Robert A. Cascella dated as of October 22, 2007.	8-K	10/22/2007
10.29*	Executive Financial Services Program.	10-K	09/27/2008
10.30	Facility Lease (Danbury) dated as of December 30, 1995 by and among Melvin J. Powers and Mary P. Powers D/B/A M&N Realty and Lorad.	Trex Medical Corporation	03/29/1996
		S-1	
10.31	Lease Agreement (Danbury and Bedford) by and between BONE (DE) QRS 15-12, INC., and Hologic dated as of August 28, 2002.	10-K	09/28/2002
10.32	First Amendment to Lease Agreement (Danbury and Bedford) by and between BONE (DE) QRS 15-12, INC., and Hologic dated as of October 29, 2007.	10-K	09/29/2007
10.33	Office Lease dated December 31, 2003 between Cytyc and Marlborough Campus Limited Partnership.	Cytyc Corporation	12/31/2003
		10-K	
10.34	Lease Agreement by and between Zona Franca Coyol S.A. and Cytyc Surgical Products Costa Rica S.A. dated April 23, 2007.	10-K	09/29/2007
10.35	Lease Agreement by and between 445 Simarano Drive, Marlborough LLC and Cytyc dated July 11, 2006.	10-K	09/29/2007
10.36	Lease Guaranty dated October 22, 2007 between Bel Marlborough I LLC and Hologic, as guarantor thereunder.	8-K	10/22/2007
10.37	Supply Agreement between Cytyc, Whatman, Inc. and Whatman SA dated as of December 31, 2000, as amended, October 16, 2001 and May 2, 2002.	Cytyc Corporation	12/31/2002
		10-K	
10.38	Form of Exchange Agreement.	8-K	11/18/2010
10.39	Hologic, Inc. 2012 Short-Term Incentive Plan	8-K	11/07/2011
12.1**	Ratio of Earnings to Fixed Charges.		
14.1	Code of Ethics for Senior Financial Officers.	8-K	10/22/2007
21.1**	Subsidiaries of Hologic.		

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Exhibit Number	Exhibit Description	Incorporated by Reference Form	Filing Date/ Period End Date
23.1**	Consent of Independent Registered Public Accounting Firm.		
31.1**	Certification of Hologic s CEO pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
31.2**	Certification of Hologic s CFO pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
32.1***	Certification of Hologic s CEO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
32.2***	Certification of Hologic s CFO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
101.INS****	XBRL Instance Document.		
101.SCH****	XBRL Taxonomy Extension Schema Document.		
101.CAL****	XBRL Taxonomy Extension Calculation Linkbase Document.		
101.DEF****	XBRL Taxonomy Extension Definition Linkbase Document.		
101.LAB****	XBRL Taxonomy Extension Label Linkbase Document.		
101.PRE****	XBRL Taxonomy Extension Presentation Linkbase Document.		

* Indicates management contract or compensatory plan or arrangement.

** Filed herewith.

*** Furnished herewith.

**** Submitted electronically herewith. Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934.

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SIGNATURES

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

HOLOGIC, INC.

By: /s/ Robert A. Cascella
Robert A. Cascella
Chief Executive Officer

Date: November 23, 2011

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Robert A. Cascella **ROBERT A. CASCELLA**	Director, President and Chief Executive Officer (Principal Executive Officer)	November 23, 2011
/s/ Glenn P. Muir **GLENN P. MUIR**	Director, Executive Vice President, Finance and Administration and Chief Financial Officer, (Principal Financial Officer)	November 23, 2011
/s/ Robert H. Lavallee **ROBERT H. LAVALLEE**	Senior Vice President, Chief Accounting Officer (Principal Accounting Officer)	November 23, 2011
/s/ David R. Lavance, Jr. **DAVID R. LAVANCE, JR.**	Chairman of the Board	November 23, 2011
/s/ Sally W. Crawford **SALLY W. CRAWFORD**	Director	November 23, 2011
/s/ Nancy L. Leaming **NANCY L. LEAMING**	Director	November 23, 2011
/s/ Lawrence M. Levy **LAWRENCE M. LEVY**	Director	November 23, 2011

/s/ CHRISTIANA STAMOULIS **CHRISTIANA STAMOULIS**	Director	November 23, 2011
/s/ ELAINE S. ULLIAN **ELAINE S. ULLIAN**	Director	November 23, 2011
/s/ WAYNE WILSON **WAYNE WILSON**	Director	November 23, 2011

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Hologic, Inc.

Consolidated Financial Statements

Years ended September 24, 2011, September 25, 2010 and September 26, 2009

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Report of Independent Registered Public Accounting Firm

on Consolidated Financial Statements

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

We have audited the accompanying consolidated balance sheets of Hologic, Inc. as of September 24, 2011 and September 25, 2010, and the related consolidated statements of operations, stockholders equity and comprehensive income (loss), and cash flows for each of the three years in the period ended September 24, 2011. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Hologic, Inc. at September 24, 2011 and September 25, 2010, and the consolidated results of its operations and cash flows for each of the three years in the period ended September 24, 2011, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for business combinations effective September 27, 2009.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Hologic, Inc. s internal control over financial reporting as of September 24, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated November 23, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

November 23, 2011

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Hologic, Inc.

Consolidated Statements of Operations

(In thousands, except per share data)

	Years ended		
	September 24, 2011	September 25, 2010	September 26, 2009
Revenues:			
Product sales	$ 1,478,340	$ 1,414,900	$ 1,426,986
Service and other revenues	311,009	264,652	210,148
	1,789,349	1,679,552	1,637,134
Costs and expenses:			
Cost of product sales	521,189	487,057	463,066
Cost of product sales amortization of intangible assets	177,456	171,447	155,519
Cost of product sales impairment of intangible assets		123,350	4,065
Cost of service and other revenues	167,523	161,060	156,998
Research and development	116,696	104,305	102,453
Selling and marketing	286,730	247,374	238,977
General and administrative	158,793	148,340	140,700
Amortization of intangible assets	58,334	54,858	51,210
Contingent consideration compensation expense	20,002		
Contingent consideration fair value adjustments	(8,016)		
Impairment of goodwill		76,723	2,340,023
Impairment of intangible assets		20,117	
Gain on sale of intellectual property, net	(84,502)		
Litigation settlement charges, net	770	11,403	
Acquired in-process research and development		2,000	
Restructuring and divestiture charges, net	(71)	1,581	797
	1,414,904	1,609,615	3,653,808
Income (loss) from operations	374,445	69,937	(2,016,674)
Interest income	1,860	1,278	1,161
Interest expense	(114,846)	(127,107)	(134,957)
Loss on extinguishment of debt	(29,891)		
Other (expense) income, net	(4,182)	901	(3,660)
Income (loss) before income taxes	227,386	(54,991)	(2,154,130)
Provision for income taxes	70,236	7,822	62,512
Net income (loss)	$ 157,150	$ (62,813)	$ (2,216,642)
Basic net income (loss) per common share	$ 0.60	$ (0.24)	$ (8.64)
Diluted net income (loss) per common share	$ 0.59	$ (0.24)	$ (8.64)
Weighted average number of common shares outstanding:			
Basic	261,099	258,743	256,545

Diluted	264,305	258,743	256,545

See accompanying notes.

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Hologic, Inc.

Consolidated Balance Sheets

(In thousands, except per share data)

	September 24, 2011	September 25, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 712,332	$ 515,625
Restricted cash	537	942
Accounts receivable, less reserves of $6,516 and $7,769 respectively	318,712	283,103
Inventories	230,544	192,482
Deferred income tax assets	39,607	72,808
Prepaid income taxes	10,098	3,944
Prepaid expenses and other current assets	31,070	29,977
Total current assets	1,342,900	1,098,881
Property and equipment, at cost:		
Land	8,883	8,882
Buildings and improvements	58,937	57,350
Equipment and software	223,403	207,382
Equipment under customer usage agreements	172,614	147,736
Furniture and fixtures	12,401	11,346
Leasehold improvements	43,554	41,130
	519,792	473,826
Less accumulated depreciation and amortization	(281,126)	(222,128)
	238,666	251,698
Intangible assets, net	2,090,807	2,118,948
Goodwill	2,290,330	2,108,847
Other assets	46,077	47,460
Total assets	$ 6,008,780	$ 5,625,834
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 63,467	$ 57,480
Accrued expenses	325,327	183,054
Deferred revenue	120,656	120,516
Deferred gain		79,500
Current portion of long-term debt		1,362
Total current liabilities	509,450	441,912
Convertible notes (principal of $1,725,000)	1,488,580	1,447,053
Deferred income tax liabilities	957,426	955,611
Deferred service obligations long-term	9,467	10,011

Other long-term liabilities	106,962	72,698
Commitments and contingencies (*Notes 12 and 15*)		
Stockholders equity		
Preferred stock, $0.01 par value 1,623 shares authorized; 0 shares issued		
Common stock, $0.01 par value 750,000 shares authorized; 262,459 and 259,488 shares issued, respectively	2,625	2,595
Capital in excess of par value	5,303,713	5,224,399
Accumulated deficit	(2,369,920)	(2,527,070)
Accumulated other comprehensive income	1,995	143
Treasury stock, at cost 219 shares	(1,518)	(1,518)
Total stockholders equity	2,936,895	2,698,549
Total liabilities and stockholders equity	$ 6,008,780	$ 5,625,834

See accompanying notes.

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Hologic, Inc.

Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss)

(In thousands, except per share data)

	Common Stock				Accumulated Other	Treasury Stock			
	Number of Shares	Par Value	Capital in Excess of Par Value	Accumulated Deficit	Comprehensive Income	Number of Shares	Amount	Total Stockholders Equity	Comprehensive Income (Loss)
Balance at September 27, 2008	256,373	$ 2,564	$ 5,137,475	$ (247,615)	$ 4,945	214	$ (1,433)	$ 4,895,936	
Exercise of stock options	1,306	13	9,379					9,392	
Issuance of common stock to employees upon vesting of restricted stock units, net of shares withheld for employee taxes	138	1	(882)					(881)	
Issuance of common shares under the employee stock purchase plan	121	1	1,541					1,542	
Stock-based compensation expense			32,939					32,939	
Excess tax benefit from employee equity awards			1,608					1,608	
Net loss				(2,216,642)				(2,216,642)	$ (2,216,642)
Foreign currency translation adjustment					1,666			1,666	1,666
Adjustment to minimum pension liability, net					417			417	417
Comprehensive loss									$ (2,214,559)
Balance at September 26, 2009	257,938	2,579	5,182,060	(2,464,257)	7,028	214	(1,433)	2,725,977	
Exercise of stock options	1,123	12	11,112					11,124	
Issuance of common stock to employees upon vesting of restricted stock units, net of shares withheld for employee taxes	331	3	(2,442)			5	(85)	(2,524)	
Issuance of common shares under the employee stock purchase plan	96	1	1,436					1,437	
Stock-based compensation expense			34,160					34,160	
Excess tax benefit from employee equity awards			757					757	
Purchase of non-controlling interest			(2,684)					(2,684)	
Net loss				(62,813)				(62,813)	$ (62,813)
Foreign currency translation adjustment					(4,763)			(4,763)	(4,763)
Adjustment to minimum pension liability, net					(2,122)			(2,122)	(2,122)
Comprehensive loss									$ (69,698)
Balance at September 25, 2010	259,488	2,595	5,224,399	(2,527,070)	143	219	(1,518)	2,698,549	
Exercise of stock options	1,779	18	23,876					23,894	
Issuance of common stock to employees upon vesting of restricted stock units, net of shares withheld for employee taxes	1,104	11	(10,410)					(10,399)	
Issuance of common shares under the employee stock purchase plan	88	1	1,509					1,510	

Stock-based compensation expense			35,472					35,472	
Reduction in excess tax benefit from employee equity awards			(5,832)					(5,832)	
Allocation of equity component related to convertible notes exchange, net of taxes			34,699					34,699	
Net income				157,150				157,150	$ 157,150
Foreign currency translation adjustment					1,088			1,088	1,088
Adjustment to minimum pension liability, net					764			764	764
Comprehensive income									$ 159,002
Balance at September 24, 2011	262,459	$ 2,625	$ 5,303,713	$ (2,369,920)	$ 1,995	219	$ (1,518)	$ 2,936,895	

See accompanying notes.

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Hologic, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Years ended		
	September 24, 2011	**September 25, 2010**	**September 26, 2009**
Operating activities			
Net income (loss)	$ 157,150	$ (62,813)	$ (2,216,642)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	68,946	68,463	67,195
Amortization	235,790	226,305	206,729
Non-cash interest expense amortization of debt discount and deferred financing costs	76,814	86,638	83,197
Impairment of goodwill		76,723	2,340,023
Impairment of intangible assets		143,467	4,065
Stock-based compensation expense	35,472	34,160	32,939
Excess tax benefit related to equity awards	(3,652)	(2,043)	(2,978)
Deferred income taxes	(48,107)	(121,726)	(26,991)
Gain on sale of intellectual property, net	(84,502)		
Loss on extinguishment of debt	29,891		
Fair value adjustments to contingent consideration	(8,016)		
Fair value write-up of inventory sold	3,298	732	1,167
Acquired in-process research and development		2,000	
Impairment of cost-method investments	2,445	1,100	2,243
Loss on disposal of property and equipment	2,639	3,765	4,430
(Gain) loss on divestiture	(354)	341	
Other non-cash activity	1,447	1,008	(1,660)
Changes in operating assets and liabilities, excluding the effect of acquisitions:			
Accounts receivable	(17,131)	(20,211)	57,581
Inventories	(32,158)	(5,247)	(14,336)
Prepaid income taxes	(6,154)	(3,772)	17,925
Prepaid expenses and other assets	(471)	(254)	(577)
Accounts payable	2,589	7,151	(12,881)
Accrued expenses and other liabilities	40,569	(348)	(10,613)
Deferred revenue	(481)	21,273	19,640
Net cash provided by operating activities	456,024	456,712	550,456
Investing activities			
Acquisition of businesses, net of cash acquired	(198,744)	(84,322)	
Payment of additional acquisition consideration	(19,660)		(229)
Divestiture activities, net of cash transferred	2,267	(1,035)	
Proceeds from sale of intellectual property	13,250	73,000	2,250
Purchase of property and equipment	(27,785)	(28,010)	(31,357)
Increase in equipment under customer usage agreements	(27,878)	(18,648)	(26,877)
Purchase of licensed technology and other intangible assets	(3,021)	(500)	(6,238)
Purchase of insurance contracts	(5,322)	(5,322)	(5,322)
Acquisition of in process research and development assets		(2,000)	
Proceeds from sale of cost method investment		678	

Purchases of cost method investments	(99)	(795)	(550)
Decrease (increase) in restricted cash	405	(26)	2,713
Net cash used in investing activities	(266,587)	(66,980)	(65,610)

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	Years ended		
	September 24, 2011	September 25, 2010	September 26, 2009
Financing activities			
Repayments under credit agreements		(174,167)	(290,833)
Payment of debt issuance costs	(5,327)		(350)
Repayments of notes payable	(1,362)	(2,837)	(10,127)
Payments upon conversion of Cytyc convertible notes			(298)
Payment of contingent consideration	(4,294)		
Purchase of non-controlling interest		(2,684)	
Net proceeds from issuance of common stock pursuant to employee stock plans	25,404	12,594	10,887
Excess tax benefit related to equity awards	3,652	2,043	2,978
Payments of employee restricted stock minimum tax withholdings	(10,399)	(2,524)	(881)
Net cash provided by (used in) financing activities	7,674	(167,575)	(288,624)
Effect of exchange rate changes on cash and cash equivalents	(404)	282	1,303
Net increase in cash and cash equivalents	196,707	222,439	197,525
Cash and cash equivalents, beginning of year	515,625	293,186	95,661
Cash and cash equivalents, end of year	$ 712,332	$ 515,625	$ 293,186

See accompanying notes.

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Hologic, Inc.

Notes to Consolidated Financial Statements

(all tabular amounts in thousands except per share data)

1. Operations

Hologic, Inc. (the Company or Hologic) develops, manufactures and distributes premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women. The Company s core business segments are focused on breast health, diagnostics, GYN surgical and skeletal health.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. The Company s fiscal year ends on the last Saturday in September. Fiscal 2011, 2010 and 2009 ended on September 24, 2011, September 25, 2010, and September 26, 2009, respectively, and each fiscal year presented included 52 weeks. Fiscal 2012 will end on September 29, 2012 and will be a 53 week fiscal period.

Management s Estimates and Uncertainties

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions by management affect the Company s revenue recognition for multiple element arrangements, allowance for doubtful accounts, the net realizable value of inventory, estimated fair value of cost-method equity investments, valuations, purchase price allocations and contingent consideration related to business combinations, expected future cash flows including growth rates, discount rates, terminal values and other assumptions and estimates used to evaluate the recoverability of long-lived assets and goodwill, estimated fair values of intangible assets and goodwill, amortization methods and periods, warranty reserves, certain accrued expenses, restructuring and other related charges, stock-based compensation, contingent liabilities, tax reserves and recoverability of the Company s net deferred tax assets and related valuation allowance.

Although the Company regularly assesses these estimates, actual results could differ materially from these estimates. Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances.

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including, dependence on third party reimbursements to support the markets of the Company s products, early stage of development of certain products, rapid technological changes, recoverability of long-lived assets (including intangible assets and goodwill), competition, stability of world financial markets, ability to obtain regulatory approvals, changes in the regulatory environment, limited number of suppliers, customer concentration, integration of acquisitions, substantial indebtedness, government regulations, future sales or issuances of its common stock, management of international activities, protection of proprietary rights, patent and other litigation and dependence on key individuals.

Cash Equivalents

Cash equivalents are highly liquid investments with insignificant interest rate risk and maturities of three months or less at the time of acquisition. At September 24, 2011 and September 25, 2010, the Company s cash equivalents consisted of money market accounts.

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Restricted Cash

Restricted cash at September 24, 2011 and September 25, 2010 is primarily comprised of various deposits for operating leases.

Concentrations of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, cost-method equity investments, and trade accounts receivable. The Company invests its cash and cash equivalents with high credit quality financial institutions.

The Company s customers are principally located in the United States, Europe and Asia. The Company performs ongoing credit evaluations of the financial condition of its customers and generally does not require collateral. Although the Company is directly affected by the overall financial condition of the healthcare industry, as well as global economic conditions, management does not believe significant credit risk exists as of September 24, 2011. The Company generally has not experienced any material losses related to receivables from individual customers or groups of customers in the health care industry. The Company maintains an allowance for doubtful accounts based on accounts past due and historical collection experience. The Company s losses related to collection of trade receivables have consistently been within management s expectations.

There were no customers with balances greater than 10% of accounts receivable as of September 24, 2011 and September 25, 2010, nor customers that represented greater than 10% of total revenues for fiscal years 2011, 2010 and 2009.

Supplemental Cash Flow Statement Information

	Years ended		
	September 24, 2011	**September 25, 2010**	**September 26, 2009**
Cash paid during the period for income taxes	$ 118,850	$ 130,486	$ 59,077
Cash paid during the period for interest	$ 36,268	$ 39,382	$ 52,001
Non-Cash Investing Activities:			
Additional acquisition contingent consideration accrued	$ 18,924	$ 32,489	$ 1,854
Non-Cash Financing Activities:			
Fair value of contingent consideration at acquisition	$ 86,600	$ 29,500	$
Deferred payment to TCT	$ 47,258	$	$
Issuance of note payable related to purchase of licensed technology	$	$	$ 3,900

Inventories

Inventories are valued at the lower of cost or market on a first in, first out basis. Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead. The valuation of inventory requires management to estimate excess and obsolete inventory. The Company employs a variety of methodologies to determine the net realizable value of its inventory. Provisions for excess and obsolete inventory are primarily based on management s estimates of forecasted net sales and service usage levels. A significant change in the timing or level of demand for the Company s products as compared to forecasted amounts may result in recording additional provisions for excess and obsolete inventory in the future. The Company records provisions for excess and obsolete inventory as cost of product sales.

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Inventories consisted of the following:

	September 24, 2011	September 25, 2010
Raw materials and work-in-process	$ 143,592	$ 124,303
Finished goods	86,952	68,179
	$ 230,544	$ 192,482

Property and Equipment

Property and equipment is recorded at cost less allowances for depreciation. The straight-line method of depreciation is used for all property and equipment. Repair and maintenance costs are expensed as incurred. Property and equipment are depreciated over the following estimated useful lives:

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

Equipment under customer usage agreements consists of diagnostic and medical imaging equipment located at customer sites but owned by the Company. Generally, the customer has the right to use it for a period of time provided they meet certain agreed to conditions.

As a result of the merger with Cytyc in fiscal 2008, the Company assumed two leases under which Cytyc or the Company disbursed cash for property and equipment to build out and equip these leased facilities. Pursuant to the provisions of ASC 840, *Leases,* Subsection 40-15-5, the Company was deemed to be the owner of the facility during the construction periods and after completion of the construction periods. As a result, these leases are not classified as operating leases but have been recorded by the Company at fair value within property and equipment on its Consolidated Balance Sheets, with an offsetting increase to accrued expenses and other long-term liabilities. Please refer to Note 12, Commitments and Contingencies , for further discussion regarding the Company s obligations under these lease agreements.

Long-Lived Assets

The Company reviews its long-lived assets, which includes property and equipment and identifiable intangible assets (see below for discussion of intangible assets), for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable in accordance with ASC 360-10-35-15, *Property, Plant and Equipment Impairment or Disposal of Long-Lived Assets* (ASC 360). Recoverability of these assets is evaluated by comparing the carrying value of the assets to the undiscounted cash flows estimated to be generated by those assets over their remaining economic life. If the undiscounted cash flows are not sufficient to recover the carrying value of

the assets, the assets are considered impaired. The impairment loss is measured by comparing the fair value of the assets to their carrying value. Fair value is determined by either a quoted market price, if any, or a value determined by a discounted cash flow technique. There were no material impairment charges related to property and equipment in fiscal 2011, 2010 and 2009. See below for discussion of impairment of intangible assets and discussion of the Conceptus litigation matter and the resulting potential indicator of impairment in the first quarter of fiscal 2012.

Business Combinations and Acquisition of Intangible Assets

The Company records tangible and intangible assets acquired in business combinations under the purchase method of accounting. The Company accounts for acquisitions in accordance with ASC 805, *Business Combinations*. The Company adopted this standard effective September 27, 2009 (fiscal 2010). Amounts paid for

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each acquisition are allocated to the assets acquired and liabilities assumed based on their fair values at the dates of acquisition. The Company allocates the purchase price in excess of the fair value of the net tangible assets acquired to identifiable intangible assets, including purchased research and development, based on detailed valuations that use certain information and assumptions provided by management. The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill. The use of alternative valuation assumptions, including estimated cash flows and discount rates, and alternative useful life assumptions could result in different purchase price allocations and intangible asset amortization expense in current and future periods.

The valuation of purchased research and development represents the estimated fair value at the dates of acquisition related to in-process projects. The Company s purchased research and development represents the value of in-process projects that have not yet reached technological feasibility and have no alternative future uses as of the date of acquisition. In connection with business combinations, the Company capitalizes the value attributable to these in-process projects at the time of the acquisition pursuant to ASC 805. Prior to the adoption of ASC 805, these in-process projects were expensed at the time of acquisition. Subsequent to acquisition, in-process research and development is evaluated as an indefinite-lived intangible asset, consistent with the accounting treatment of goodwill. No additional amounts are capitalized and once the project is completed the asset is amortized over its estimated useful life. If the projects are not successful or completed in a timely manner, the Company may not realize the financial benefits expected for these projects or for the acquisitions as a whole and impairments may result.

The Company uses the income approach to determine the fair values of its purchased research and development. This approach determines fair value by estimating the after-tax cash flows attributable to an in-process project over its useful life and then discounting these after-tax cash flows back to a present value. The Company bases its revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology and expected product introductions by competitors. In arriving at the value of the in-process projects, the Company considers, among other factors, the in-process projects stage of completion, the complexity of the work completed as of the acquisition date, the costs already incurred, the projected costs to complete, the contribution of core technologies and other acquired assets, the expected introduction date and the estimated useful life of the technology. The Company bases the discount rate used to arrive at a present value as of the date of acquisition on the time value of money and medical technology investment risk factors. The Company believes that the estimated purchased research and development amounts so determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the projects.

The Company also uses the income approach, as described above, to determine the estimated fair value of certain other identifiable intangible assets including developed technology, customer relationships, trade names and business licenses. Developed technology represents patented and unpatented technology and know-how. Customer relationships represent established relationships with customers, which provide a ready channel for the sale of additional products and services. Trade names represent acquired company and product names.

Intangible Assets and Goodwill

Intangible Assets

Intangible assets are recorded at fair value and stated net of accumulated amortization and impairments. The Company amortizes its intangible assets that have finite lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from 2 to 30 years. The Company evaluates the realizability of its definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair

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of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, the Company uses market participant assumptions pursuant to ASC 820, *Fair Value Measurements*.

If the estimate of an intangible asset s remaining useful life is changed, the Company will amortize the remaining carrying value of the intangible asset prospectively over the revised useful life.

During the fourth quarter of fiscal 2010 in connection with the Company-wide annual budgeting and strategic planning process, the Company determined that indicators of impairment existed in its MammoSite reporting unit, which is included in the Breast Health reportable segment. The impairment indicators were due to changing market conditions for the breast brachytherapy market, 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. These factors resulted in the Company lowering its financial projections for MammoSite. As a result, the Company performed the first step in the long-lived assets impairment test pursuant to ASC 360 and compared MammoSite s forecasted undiscounted cash flows to the carrying value of its net assets. These cash flows were insufficient to recover MammoSite s carrying value. Therefore, the Company determined the fair value of MammoSite s long-lived assets, which are primarily intangible assets, using a discounted cash flow technique. The expected future cash flows are Level 3 inputs under ASC 820 and are those expected to be generated by market participants. Based on the estimated fair value of the long-lived assets, the Company recorded an aggregate impairment charge of $143.5 million to write down these intangible assets to their fair value. The charge was comprised of $123.4 million related to developed technology, which was recorded in cost of product sales in the Consolidated Statement of Operations, $11.8 million related to customer relationships and $8.3 million related to trade names, which were recorded in impairment of intangible assets in the Consolidated Statements of Operations. In addition, the Company recorded a goodwill impairment charge of $76.7 million (see below for further discussion).

During the second quarter of fiscal 2009, as a result of the Company s conclusion that an interim impairment test of goodwill was required as of December 27, 2008 (as discussed below), the Company performed an impairment test of certain long-lived assets as of December 27, 2008. The impairment evaluation was based on expectations of future undiscounted cash flows compared to the carrying value of the long-lived asset groups. The Company s cash flow estimates were based upon historical cash flows, as well as future projected cash flows derived from the Company-wide annual planning process and updated interim forecasting process. The Company believed that its procedures for estimating future cash flows were reasonable and consistent with market conditions at the time of estimation. The results of the Company s interim impairment testing indicated that there was no impairment of its long-lived assets as of December 27, 2008.

During the second quarter of fiscal 2009, the Company decided to discontinue selling a certain product within the Diagnostic reporting segment as a result of communications from the FDA regarding the approval process. The Company performed an impairment test in accordance with ASC 360. The Company determined that the asset group s fair value was de minimus and recorded an impairment charge of $4.1 million comprised of developed technology of $2.6 million and capitalized license fees of $1.5 million. This charge is reflected in cost of product sales in the Consolidated Statement of Operations.

During the fourth quarter of fiscal 2010, the Company acquired certain in-process research and development assets. Since these assets had no alternative future use, the Company recorded an in-process research and development charge of $2.0 million.

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Intangible assets consist of the following:

	As of September 24, 2011		As of September 25, 2010	
Description	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Developed technology	$ 2,215,323	$ 586,647	$ 2,047,613	$ 410,801
In-process research and development	840		4,760	
Customer relationships	507,974	150,039	471,468	105,059
Trade names	142,799	44,267	138,914	30,154
Patents	9,937	7,752	9,583	7,659
Business licenses	2,535	81		
Non-compete agreements	297	112	297	14
	$ 2,879,705	$ 788,898	$ 2,672,635	$ 553,687

During 2011, both of the in-process research and development projects form the Sentinelle acquisition were completed and transferred to developed technology.

Amortization expense related to developed technology and patents is classified as a component of cost of product sales amortization of intangible assets in the Consolidated Statements of Operations. Amortization expense related to customer relationships, trade names, business licenses and non-competes is classified as a component of amortization of intangible assets in the Consolidated Statements of Operations.

The estimated amortization expense at September 24, 2011 for each of the five succeeding fiscal years is as follows:

Fiscal 2012	$ 242,949
Fiscal 2013	231,812
Fiscal 2014	217,251
Fiscal 2015	202,311
Fiscal 2016	188,542

Goodwill

In accordance with ASC 350, *Intangibles Goodwill and Other* (ASC 350), the Company tests goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business, and an adverse action or assessment by a regulator.

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

primarily utilizes the income approach. The income approach is based on a discounted cash flow analysis (DCF) and calculates the fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting the after-tax cash flows to a present value using a risk-adjusted discount rate. Assumptions used in the DCF require significant judgment, including judgment about appropriate discount rates and terminal values, growth rates, and the amount and timing of expected future cash flows. The forecasted cash flows are based on the Company s most recent budget and for years beyond the budget, the Company s estimates are based on assumed growth rates. The Company believes its assumptions are consistent with the plans and estimates used to manage the underlying businesses. The discount

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rates, which are intended to reflect the risks inherent in future cash flow projections, used in the DCF are based on estimates of the weighted-average cost of capital (WACC) of market participants relative to each respective reporting unit. The market approach considers comparable market data based on multiples of revenue or earnings before interest, taxes, depreciation and amortization (EBITDA) and is primarily used as a corroborative analysis to the results of the DCF. The Company believes its assumptions used to determine the fair value of its respective reporting units are reasonable. If different assumptions were used, particularly with respect to forecasted cash flows, terminal values, WACCs, or market multiples, different estimates of fair value may result and there could be the potential that an impairment charge could result. Actual operating results and the related cash flows of the reporting units could differ from the estimated operating results and related cash flows.

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

The Company conducted its fiscal 2011 annual impairment test on the first day of the fourth quarter. The Company utilized DCF and market approaches to estimate the fair value of its reporting units as of June 26, 2011, and ultimately used the fair value determined by the DCF in making its impairment test conclusions. The Company believes it has used reasonable estimates and assumptions about future revenue, cost projections, cash flows and market multiples. In addition, using a DCF requires the use of a risk-adjusted discount rate for which the Company based its rate on the WACC of market participants. As a result of completing Step 1, all of the Company s reporting units had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required. For illustrative purposes, had the fair value of each reporting unit been lower by 10%, each reporting unit would have still passed Step 1 of the goodwill impairment test.

The Company has ongoing litigation with Conceptus regarding potential patent infringement of a Conceptus patent by the Company s Adiana Permanent Contraception system (see Note 15). In the first quarter of fiscal 2012, the jury returned a verdict in favor of Conceptus and awarded Conceptus $18.8 million in damages. Post trial motions will be filed addressing certain issues that could impact the ultimate outcome of this case. The Company also expects that Conceptus will seek to enjoin it from further sales of the Adiana system. A hearing on the post trial motions and injunctions request is scheduled for December 22, 2011. The jury verdict and any such determinations are subject to appeal by either party. If Conceptus is successful in upholding the verdict, the Company may be required to remove the Adiana system from the market. This jury verdict and subsequent litigation status may be an indicator of impairment for the Company s GYN Surgical reporting unit. A reduction in the anticipated future cash flows of the GYN Surgical reporting unit could result in a material impairment charge that would have an adverse impact on its operating results. The Company will further evaluate this matter in the first quarter of fiscal 2012 and will perform an interim goodwill impairment analysis and a long-lived asset impairment analysis, if required.

The Company conducted its fiscal 2010 annual impairment test on the first day of the fourth quarter. The Company utilized DCF and market approaches to estimate the fair value of its reporting units as of June 27, 2010, and ultimately used the fair value determined by the DCF in making its impairment test conclusions. The Company believed it used reasonable estimates and assumptions about future revenue, cost projections, cash flows and market multiples. In addition, using a DCF requires the use of a risk-adjusted discount rate for which the Company based its rate on the WACC of market participants. As a result of completing Step 1, all of the Company s reporting units, except MammoSite, had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required for these reporting units. MammoSite s fair value has declined from fiscal 2009 primarily due to a reduction in its long-term growth rates. The changes in MammoSite s financial projections are a result of changing market conditions for the brachytherapy market, including downward pressure on procedure volumes due to the continuing adverse economic environment and current

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trends in breast cancer management, as well as competitive pricing pressures and competition from existing and alternative new technologies. The DCF calculation of fair value was positively impacted by a reduction in the discount rate to 11.0% from 12.5% used in the fiscal 2009 annual impairment test due to slight overall improvements in economic conditions and changes in the financial projections.

The Company performed the Step 2 analysis for MammoSite, consistent with the procedures described above, and recorded a $76.7 million impairment charge. For illustrative purposes had the fair value of MammoSite been 10% lower, the charge would have been higher by $2.5 million. If the fair value of the Company s other reporting units had been lower by 10%, one reporting unit would have failed Step 1 requiring a Step 2 analysis. This reporting unit is in the Breast Health reportable segment and had a fair value at the annual impairment measurement date that exceeded its carrying value by 4% with goodwill of $256.5 million. The fair value of the reporting unit is determined by use of the DCF, and the key assumptions that drive the fair value in this model are the WACC, terminal values, growth rates, and the amount and timing of expected future cash flows. If the current economic environment were to deteriorate, this would likely result in a higher WACC because market participants would require a higher rate of return. In the DCF as the WACC increases, the fair value decreases. The other significant factor in the DCF is the projected financial information (i.e., amount and timing of expected future cash flows and growth rates) and if these assumptions were to be adversely impacted, this could result in a reduction of the fair value of this reporting unit. At September 25, 2010, for the Company s other reporting units with goodwill aggregating $1.85 billion, the Company believed that these reporting units are not at risk of failing Step 1 of the goodwill impairment test.

The Company conducted its fiscal 2009 annual impairment test for its reporting units as of the first day of the fourth quarter. In order to complete the annual impairment test, the Company updated its interim impairment test results (see below) and performed detailed analysis estimating the fair value of its reporting units utilizing its fiscal 2010 forecast with updated long-term growth assumptions. For one reporting unit, the Company utilized the results of its interim impairment test. The Company concluded that it met the required criteria to use the estimated fair value determined from its interim impairment analysis for this reporting unit because 1) the composition of the assets and liabilities of this reporting unit had not changed significantly since the most recent fair value determination, 2) the most recent fair value determination resulted in a fair value that exceeded the carrying value of the reporting unit by a substantial margin after consideration of the interim goodwill charge, and 3) management concluded, based on an analysis of current events that had occurred and circumstances that had changed since the most recent fair value determination, that it was remote that the current fair value of the reporting unit would not exceed its carrying amount.

As a result of completing Step 1, all of the Company s reporting units, except one, had a fair value exceeding its carrying value, and as such, Step 2 of the impairment test was not required for these reporting units. For the reporting unit that failed Step 1, the Company completed Step 2, consistent with the procedures described above, and determined that an impairment charge was not required due to the fair value of the implied goodwill exceeding the carrying value of the reporting unit s goodwill. If the fair value of this reporting unit at June 28, 2009 had been lower by 10%, the Company still would not have recorded an impairment charge.

During the first quarter of fiscal 2009, based upon a combination of factors, including the deteriorating macro-economic environment, declines in the stock market and the decline of the Company s market capitalization significantly below the book value of the Company s net assets, the Company concluded that potential goodwill impairment indicators existed as of December 27, 2008. As a result, the Company performed an interim goodwill impairment analysis as of December 27, 2008 in accordance with ASC 350. The Company utilized DCF and market approaches to estimate the fair value of its reporting units as of December 27, 2008 and believes it has used reasonable estimates and assumptions about future revenue, cost projections, cash flows and market multiples. In addition, using a DCF requires the use of a risk-adjusted discount rate for which the Company based its rate on the WACC of market participants. The Company performed a peer company analysis and considered the industry weighted average return on debt and equity from a market participant perspective for its reporting units. Given the disruptions in the credit and equity markets, the WACCs for each reporting unit

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increased between the Company s annual test performed on the first day of its fourth quarter of fiscal 2008 and the interim test performed as of December 27, 2008. The long-term growth rates were largely consistent with those applied in the fiscal 2008 annual test, except for MammoSite, in which the long-term growth rate declined due to competitive pressures on the reporting unit s products, as well as regulatory and reimbursement changes. The Step 1 impairment analysis indicated that the carrying value of the net assets of three of the Company s reporting units, acquired in connection with the Cytyc acquisition, exceeded the estimated fair value of those reporting units. As a result, the Company was required to perform Step 2 of the goodwill impairment test to determine the amount, if any, of goodwill impairment charges for each of the applicable reporting units. Due to the complexities and time involved in preparing the Step 1 analysis, the Company had not commenced the Step 2 analysis as of February 5, 2009, the date it filed its Form 10-Q for the quarter ended December 27, 2008. As a result of the fact that the Company had not commenced the Step 2 analysis and the complexity of the analysis required to complete the Step 2 analysis, the Company was unable to determine that an impairment loss, in accordance with ASC 450, *Contingencies*, was both probable and reasonably estimable at December 27, 2008.

The Company completed the Step 2 analysis during its second quarter of fiscal 2009, which resulted in an aggregate goodwill impairment charge of $2.34 billion. This impairment charge was comprised of $1.17 billion for GYN Surgical, $908.3 million for Diagnostics, and $265.9 million for Breast Health. The impairment charges for GYN Surgical and Diagnostics were primarily attributable to the assumption of higher discount rates compared to those used in the annual impairment test performed as of the first day of the fourth quarter of fiscal 2008 (the July 2008 valuation) and the assumption that the reporting units would be purchased or sold in a taxable transaction. The impairment charge for MammoSite was a result of a combination of a higher discount rate and lower projected future cash flows compared to those used in the July 2008 valuation. The higher discount rates for the three reporting units, which range from 10% to 13.5% compared to 9% to 10% used in the July 2008 valuation, reflected an increase in the risks inherent in the estimated future cash flows and the higher rate of return a market participant would require based on the macro-economic environment at the measurement date. The reduction in forecasted cash flows for the MammoSite reporting unit was due to competitive pressure on the reporting unit s products as well as regulatory and reimbursement changes that occurred during fiscal 2009.

The Company also evaluated the aggregate fair value of its reporting units compared to its market capitalization noting an implied control premium of approximately 16% at December 27, 2008. The Company used an average of its market capitalization over the 30 calendar days preceding the impairment testing date as being more reflective of its market value than a single day, point-in-time market price. The Company concluded that its implied control premium was reasonable when compared to industry specific information.

For illustrative purposes, had the fair values of each reporting unit for which the Company has recorded goodwill impairment charges in the second quarter of fiscal 2009 been lower by 10% as of December 27, 2008, the Company would have recorded an additional impairment charge of $435.5 million. Based on the Company s estimates as of December 27, 2008, the impact of reducing the Company s fair value estimates for its other reporting units, for which the Company did not record any goodwill impairment charges, by 10% would have had no impact on the Company s goodwill assessment for those reporting units.

The Company believes that the procedures performed and the estimates and assumptions used in the Step 1 and Step 2 analyses for each reporting unit are reasonable and in accordance with the guidelines for acquisition accounting under U.S. generally accepted accounting principles. The estimate of fair value requires significant judgment. The impairment testing process is subjective and requires judgment at many points throughout the analysis. If these estimates or their related assumptions change in the future, the Company may be required to record impairment charges for these assets not previously recorded.

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A rollforward of goodwill activity from September 26, 2009 to September 24, 2011 is as follows:

Balance as of September 26, 2009	$ 2,108,963
Impairment of goodwill	(76,723)
Sentinelle Medical acquisition	48,617
Accrued contingent consideration	32,489
Other adjustments, including taxes	(3,561)
Foreign currency translation adjustment	(938)
Balance as of September 25, 2010	2,108,847
Interlace acquisition	88,279
TCT acquisition	77,870
Healthcome acquisition	5,799
Accrued contingent consideration	18,924
Other adjustments, including taxes	(10,466)
Foreign currency translation adjustment	1,077
Balance as of September 24, 2011	$ 2,290,330

Accumulated goodwill impairment losses at September 24, 2011 were $2.42 billion. The allocation of goodwill by reporting segment consisted of the following:

Reporting Segment	September 24, 2011	September 25, 2010
Breast Health	$ 638,887	$ 633,393
Diagnostics	633,319	577,205
GYN Surgical	1,009,973	890,098
Skeletal Health	8,151	8,151
	$ 2,290,330	$ 2,108,847

Other Assets

As of September 24, 2011 and September 25, 2010, other assets were comprised primarily of Company owned life insurance contracts, deferred financing costs, and cost-method investments.

The Company owned life insurance contracts were purchased in connection with the Company s Nonqualified Deferred Compensation Plan (DCP) and were valued at $22.7 million and $18.2 million as of September 24, 2011 and September 25, 2010, respectively (See Note 11 for further discussion).

As of September 24, 2011 and September 25, 2010, other assets included $11.9 million and $15.6 million, respectively, of deferred financing costs related to the Company s Convertible Notes. The Company is amortizing amounts related to the Convertible Notes using the effective interest rate method over the period of earliest redemption.

Other assets also include certain other cost-method equity investments in non-publicly traded equity securities aggregating $4.6 million and $7.0 million for fiscal 2011 and 2010, respectively. These investments are generally carried at cost as the Company owns less than 20% of the voting equity and does not have the ability to exercise significant influence over these companies. The Company regularly evaluates the carrying value of its cost-method equity investments for impairment and whether any events or circumstances are identified that would significantly harm the fair value of the investment. The primary indicators the Company utilizes to identify these events and circumstances are the investee s ability to remain in business, such as the investee s liquidity and rate of cash use, and the investee s ability to secure additional funding and the value of that additional funding. In the event a decline in fair value is judged to be other-than-temporary, the Company will

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record an other-than-temporary impairment charge in other income (expense), net in the Consolidated Statements of Operations. During fiscal 2011, 2010 and 2009, the Company recorded other-than-temporary impairment charges of $2.4 million, $1.1 million and $2.2 million, respectively, related to certain of its cost-method equity investments to adjust their carrying amounts to fair value.

Research and Software Development Costs

Costs incurred for the research and development of the Company s products are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future by the Company for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. If the Company s expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments are recorded to expense in that period.

The Company accounts for the development costs of software embedded in the Company s products for which revenues are recognized pursuant to ASC 985-605, *Software Revenue Recognition*, in accordance with ASC 985, *Software.* Costs incurred in the research, design and development of software embedded in products to be sold to customers are charged to expense until technological feasibility of the ultimate product to be sold is established. Software development costs incurred after the establishment of technological feasibility and until the product is available for general release are capitalized, provided recoverability is reasonably assured. Software development costs eligible for capitalization have not been significant to date.

Foreign Currency Translation

The financial statements of the Company s foreign subsidiaries are translated in accordance with ASC 830, *Foreign Currency Matters.* The reporting currency for the Company is the U.S. dollar. With the exception of its Costa Rica subsidiary, whose functional currency is the U.S. dollar, the functional currency of the Company s foreign subsidiaries is their local currency. Accordingly, assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each balance sheet date. Before translation, the Company re-measures foreign currency denominated assets and liabilities, including inter-company accounts receivable and payable, into the functional currency of the respective entity, resulting in unrealized gains or losses recorded in other income (expense), net in the Consolidated Statement of Operations. Revenues and expenses are translated using average exchange rates during the respective period. Foreign currency translation adjustments are accumulated as a component of other comprehensive income as a separate component of stockholders equity. Gains and losses arising from transactions denominated in foreign currencies are included in other income (expense), net on the Consolidated Statements of Operations and to date have not been material.

Comprehensive Income (Loss)

ASC 220, *Comprehensive Income,* requires the financial statements to include the reporting of comprehensive income (loss), which includes net income (loss) and certain transactions that have generally been reported in the statement of shareholders equity. Comprehensive income (loss) is disclosed in the Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss).

Accumulated other comprehensive income consists of the following:

	September 24, 2011	September 25, 2010
Foreign currency translation adjustment	$ 994	$ (94)
Minimum pension liability, net of tax of $300 and $102, respectively	1,001	237
	$ 1,995	$ 143

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Revenue Recognition

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

In September 2009, the FASB ratified ASC Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13). ASU 2009-13 amends existing revenue recognition accounting standards that are currently within the scope of ASC, Subtopic 605-25, which is the revenue recognition standard for multiple-element arrangements. ASU 2009-13 provides for three significant changes to the existing multiple element revenue recognition guidance as follows:

1) Removes the requirement to have objective and reliable evidence of fair value for undelivered elements in an arrangement. This may result in more deliverables being treated as separate units of accounting.

2) Modifies the manner in which the arrangement consideration is allocated to the separately identified deliverables. ASU 2009-13 requires an entity to allocate revenue in an arrangement using its best estimate of selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE), if VSOE is not available. Each separate unit of accounting must have a selling price, which can be based on management s estimate when there is no other means (VSOE or TPE) to determine the selling price of that deliverable. The arrangement consideration is allocated based on the elements relative selling prices.

3) Eliminates use of the residual method and requires an entity to allocate revenue using the relative selling price method, which results in the discount in the transaction being evenly allocated to the separate units of accounting.

In September 2009, the FASB ratified ASU No. 2009-14, *Certain Revenue Arrangements that Include Software Elements* (ASU 2009-14). ASU 2009-14 amends the existing revenue recognition accounting standards to remove tangible products that contain software components and non-software components that function together to deliver the product s essential functionality from the scope of industry specific software revenue recognition guidance.

As permitted, the Company elected to early adopt these new accounting standards at the beginning of its first quarter of fiscal 2010 on a prospective basis for transactions originating or materially modified on or after September 27, 2009. These accounting standards generally do not change the units of accounting for the Company s revenue transactions, and most products and services qualify as separate units of accounting. The impact of adopting these new accounting standards was not material to the Company s financial statements for the year ended September 25, 2010, and if they were applied in the same manner to fiscal 2009, they would not have had a material impact to revenue recorded in fiscal 2009 or any interim period therein.

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

delivered. There is no customer right of return in the Company s sales agreements.

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Service revenues primarily consist of amounts recorded under service and maintenance contracts and repairs not covered under warranty, installation and training, and shipping and handling costs billed to customers. Service and maintenance contract revenues are recognized ratably over the term of the contract. Other service revenues are recognized as the services are performed.

The Company typically determines the selling price of its products and services based on VSOE. The Company determines VSOE based on its normal pricing and discounting practices for the specific product or service when sold on a stand-alone basis. In determining VSOE, the Company s policy requires a substantial majority of selling prices for a product or service to be within a reasonably narrow range. The Company also considers the class of customer, method of distribution, and the geographies into which its products and services are sold when determining VSOE. The Company typically has had VSOE for its products and services.

If VSOE cannot be established, which may occur in instances when a product or service has not been sold separately, stand-alone sales are too infrequent, or product pricing is not within a narrow range, the Company attempts to establish the selling price based on TPE. TPE is determined based on competitor prices for similar deliverables when sold separately.

When the Company cannot determine VSOE or TPE, it uses ESP in its allocation of arrangement consideration. The objective of ESP is to determine the price at which the Company would typically transact a stand-alone sale of the product or service. ESP is determined by considering a number of factors including Company pricing policies, internal costs and gross margin objectives, method of distribution, information gathered from experience in customer negotiations, market research and information, recent technological trends, competitive landscape and geographies.

Some of the Company s products have both software and non-software components that function together to deliver the product s essential functionality. Prior to the adoption of ASU 2009-14, the Company had determined that except for its computer-aided detection (CAD) products and Dimensions 2D/3D full field digital mammography products (Dimensions), the software element in its other products was incidental in accordance with the software revenue recognition rules and were not within the scope of the software revenue recognition rules, ASC 985-605, *Software Revenue Recognition*. The Company had determined that given the significance of the software component s functionality to its CAD systems and Dimensions products, which are in the Breast Health segment, these products were within the scope of the software revenue recognition rules.

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

Upon the release of the Dimensions product in fiscal 2009, the Company completed an evaluation of the software component in accordance with the software revenue recognition rules. As a result, the Company had determined that the Dimensions product contained software that was more than incidental to the product as a whole and should be accounted for under the software revenue recognition rules.

In connection with its adoption of ASU 2009-14, the Company re-evaluated the appropriate revenue recognition treatment of its products and determined that the Dimensions products, which have both software and non-software components that function together to deliver the products essential functionality (i.e., it is a tangible product), are scoped out of ASC 985-605, however, its CAD products will continue to be subject to ASC 985-605. Dimensions transactions entered into prior to the first quarter of fiscal 2010 will continue to be accounted for under ASC

985-605.

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Under customer usage agreements, the Company installs certain equipment (for example, a ThinPrep Processor or a ThinPrep Imaging System) at customer sites and customers commit to purchasing minimum quantities of disposable products at a stated price (generally including a usage fee for the equipment) over a defined contract term, which is typically between three and five years. Revenue is recognized over the term of the customer usage agreement as disposable products are delivered. The Company also rents certain equipment to customers. Revenues from rental agreements are recorded over the term of the rental agreements.

Accounts Receivable and Reserves

The Company records reserves for doubtful accounts based upon a specific review of all outstanding invoices, known collection issues and historical experience. The Company regularly evaluates the collectability of its trade accounts receivables and performs ongoing credit evaluations of its customers and adjusts credit limits based upon payment history and its assessment of the customer s current credit worthiness. These estimates are based on specific facts and circumstances of particular orders, analysis of credit memo data and other known factors.

Accounts receivable reserve activity for fiscal years 2011, 2010 and 2009 is as follows:

	Balance at Beginning of Period	Charged to Costs and Expenses	Write-offs and Payments	Balance at End of Period
Period Ended:				
September 24, 2011	$ 7,769	$ 1,614	$ (2,867)	$ 6,516
September 25, 2010	$ 7,279	$ 1,895	$ (1,405)	$ 7,769
September 26, 2009	$ 6,326	$ 2,334	$ (1,381)	$ 7,279

Cost of Service and Other Revenues

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

Stock-Based Compensation

The Company accounts for share-based payments in accordance with ASC 718, *Stock Compensation.* As such, all share-based payments to employees, including grants of stock options and restricted stock units, are recognized in the consolidated statement of operations based on their fair values as the date of grant.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares and potential common shares from outstanding stock options, restricted stock units and convertible debt determined by applying the treasury stock method. In accordance with ASC 718, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of in-the-money stock options and restricted stock units.

The Company applies the provisions of ASC 260, *Earnings Per Share,* Subsection 10-45-44, to determine the diluted weighted average shares outstanding as it relates to its Convertible Notes, and due to the type of debt instrument issued, the Company applies the treasury stock method and not the if-converted method. The dilutive impact of the Company s Convertible Notes is based on the difference between the Company s current period average stock price and the conversion price of the Convertible Notes, provided there is a premium. Pursuant to this accounting standard, there is no dilution from the accreted principal of the Convertible Notes.

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A reconciliation of basic and diluted share amounts for fiscal years 2011, 2010, and 2009 is as follows:

	September 24, 2011	September 25, 2010	September 26, 2009
Numerator:			
Net income (loss)	$ 157,150	$ (62,813)	$ (2,216,642)
Denominator:			
Basic weighted average common shares outstanding	261,099	258,743	256,545
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock units	3,206		
Diluted weighted average common shares outstanding	264,305	258,743	256,545
Basic net income (loss) per common share	$ 0.60	$ (0.24)	$ (8.64)
Diluted net income (loss) per common share	$ 0.59	$ (0.24)	$ (8.64)
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	7,747	13,260	13,489
Restricted stock units		1,427	1,575

In those reporting periods in which the Company has reported net income, anti-dilutive shares comprise those common stock equivalents that have either an exercise price above the average stock price for the period or the common stock equivalents related average unrecognized stock compensation expense is sufficient to buy back more than the entire amount of shares. In those reporting periods in which the Company has a net loss, anti-dilutive shares comprise the impact of those number of shares that would have been dilutive had the Company had net income plus the number of common stock equivalents that would be anti-dilutive had the company had net income.

Product Warranties

The Company generally offers a one-year warranty for its products. The Company provides for the estimated cost of product warranties at the time product revenue is recognized. Factors that affect the Company s warranty reserves include the number of units sold, historical and anticipated rates of warranty repairs and the cost per repair. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary.

Product warranty activity for fiscal 2011 and 2010 is as follows:

	Balance at Beginning of Period	Provisions	Acquired	Settlements/ adjustments	Balance at End of Period
Period end:					
September 24, 2011	$ 2,830	$ 5,535	$ 657	$ (4,574)	$ 4,448
September 25, 2010	$ 5,602	$ 3,994	$ 99	$ (6,865)	$ 2,830

Restructuring and Divestiture Charges and Accrual

In the fourth quarter of fiscal 2011, the Company terminated the employment of certain individuals and recorded a severance and benefits charge of $0.3 million, all of which was unpaid as of September 24, 2011. In addition, in the fourth quarter of fiscal 2011, the Company sold a minor non-core product line for $1.1 million resulting in a net gain of $0.4 million.

In the fourth quarter of fiscal 2010, the Company terminated the employment of certain employees in connection with completing the Sentinelle Medical acquisition. As a result, the Company recorded a severance and benefits charge of $0.9 million.

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In the fourth quarter of fiscal 2009, the Company closed its organic photoconductor drum coatings manufacturing facility in Shanghai, China and recorded restructuring charges for severance benefits of $0.4 million and other costs of $0.4 million. These severance benefits were paid to the employees as of September 26, 2009. In connection with this action, the Company ceased production during the fourth quarter of 2009 and recorded impairment charges of $0.7 million in cost of product sales for manufacturing equipment that had no further utility. As a result of closing this facility, the Company recorded net charges of $0.4 million in fiscal 2010. In the second quarter of fiscal 2010, the Company completed the sale of the capital stock of this manufacturing operation for a net sales price of $3.8 million resulting in a loss on divestiture of $0.3 million. The Company received $2.7 million in fiscal 2010 and the remainder of the sales price of $1.1 million was received in the first quarter of fiscal 2011.

Advertising Costs

Advertising costs are charged to operations as incurred. The Company does not have any direct-response advertising. Advertising costs, which include trade shows and conventions, were approximately $25.9 million, $12.1 million and $12.4 million for fiscal 2011, 2010 and 2009, respectively, and were included in selling and marketing expense in the Consolidated Statements of Operations.

Recently Issued Accounting Pronouncements

Presentation of Comprehensive Income

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 is effective for the Company in its first quarter of fiscal 2013 and should be applied retrospectively. The Company is currently evaluating the impact of the adoption of ASU 2011-05 on its consolidated financial statements.

Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements

In May 2011, the FASB issued ASU No. 2011-04 *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 is effective for the Company in its second quarter of fiscal 2012 and should be applied prospectively. The Company is currently evaluating the impact of the adoption of ASU 2011-04 on its consolidated financial statements.

Business Combinations

In December 2010, the FASB issued ASU No. 2010-29, *Business Combinations (ASC Topic 805) Disclosure of Supplementary Pro Forma Information for Business Combinations*. ASU 2010-29 requires a public entity to disclose revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the prior year. It also requires a description of the nature and amount of material, nonrecurring adjustments directly attributable to the business combination included in the reported revenue and earnings. The new disclosure will be effective for the Company s first quarter of fiscal 2012. The adoption of ASU 2010-29 will require additional disclosure in the event of a business combination but will not have a material impact on the Company s consolidated financial statements.

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Intangibles Goodwill and Other

In December 2010, the FASB issued ASU 2010-28, *Intangibles- Goodwill and Other (ASC Topic 350)*. ASU 2010-28 modifies Step 1 of the goodwill impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. ASU 2010-28 is effective for the Company in fiscal 2012. The Company does not believe that ASU 2010-28 will have a material impact on its consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. ASU 2011-08 allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. ASU 2011-08 is effective for the Company beginning in fiscal 2013, although early adoption is permitted. The Company does not believe that ASU 2011-08 will have a material impact on its consolidated financial statements.

3. Business Combinations

Fiscal 2011 Acquisitions:

TCT International Co., Ltd.

On June 1, 2011, the Company completed the acquisition of 100% of the equity interest in TCT International Co., Ltd. (TCT) and subsidiaries, a privately-held distributor of medical products, including the Company s ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT s operating subsidiaries are located in Beijing, China. The Company s acquisition of TCT has enabled it to obtain an established nationwide sales organization and customer support infrastructure in China, which is consistent with the Company s international expansion strategy. TCT has been integrated within the Company s international operations, and its results are primarily reported within the Company s Diagnostics reporting segment and to a lesser extent within the Company s GYN Surgical reporting segment.

The Company concluded that the acquisition of TCT did not represent a material business combination, and therefore, no pro forma financial information has been provided herein. Subsequent to the acquisition date, the Company s results of operations include the results of TCT. The Company accounted for the TCT acquisition as a purchase of a business under ASC 805, *Business Combinations*.

The preliminary purchase price of $147.3 million is comprised of $135.0 million in cash, of which $100.0 million was paid up-front and $35.0 million plus a working capital adjustment, which has been preliminarily estimated to be $13.0 million, are deferred for one year. This amount may be subject to further adjustment. The deferred payment has been recorded on a present value basis of $47.3 million in purchase accounting to reflect fair value and such payment is being accreted through interest expense over this one year period. In addition, the majority of the former shareholders of TCT will receive two annual contingent earn-out payments (subject to adjustment) not to exceed $200.0 million less the deferred payment. The contingent earn-out payments are based on a multiple of incremental revenue growth for the one year periods beginning January 1, 2011 and January 1, 2012 as compared to the respective prior year periods, and are payable after the first and second anniversaries from the date of acquisition, respectively. Since these payments are contingent on future employment, they are being recognized as compensation expense

ratably over the required service periods, the first and second year anniversaries from the date of acquisition. Based on its revenue projections for the TCT business, the Company has recorded compensation expense of $17.6 million for these contingent payments in fiscal 2011.

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The Company did not issue any equity awards in connection with this acquisition. The Company incurred third-party transaction costs of $1.3 million, which were expensed within general and administrative expenses primarily in fiscal 2011.

The allocation of the preliminary purchase price was based on preliminary estimates of the fair value of assets acquired and liabilities assumed as of June 1, 2011. The Company is continuing to obtain information to complete its valuation of intangible assets, as well as to determine the acquired assets and liabilities, including tax assets and liabilities. The components and allocation of the preliminary purchase price consists of the following approximate amounts:

Cash	$ 27,961
Accounts receivable	18,032
Inventory, including fair value adjustments	5,469
Property and equipment	4,039
Other tangible assets	1,081
Accrued taxes	(14,399)
Accounts payable and accrued expenses	(7,517)
Customer relationships	41,800
Business licenses	2,500
Trade names	1,900
Deferred taxes, net	(11,445)
Goodwill	77,870
Purchase Price	$ 147,291

As part of the preliminary purchase price allocation, the Company determined that the separately identifiable intangible assets were customer relationships, business licenses, and trade names related to the TCT company name. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted at 12.5%. Customer relationships relate to relationships that TCT s founders and sales force have developed with obstetricians, gynecologists, hospitals, and clinical laboratories.

Customer relationships, business licenses and trade names are being amortized over a weighted average period of 13.6 years, 10 years and 13 years, respectively.

The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to the established sales and distribution network of TCT and expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

Interlace Medical, Inc.

On January 6, 2011, the Company consummated the acquisition of 100% of the equity interest in Interlace Medical, Inc. (Interlace), a privately-held company located in Framingham, Massachusetts. Interlace is the developer, manufacturer and supplier of the MyoSure hysteroscopic tissue removal system (MyoSure). The MyoSure system is a new and innovative tissue removal device that is designed to provide incision-less removal of fibroids and polyps within the uterus. Interlace s operations have been integrated within the Company s GYN Surgical reporting segment. The Company believes that MyoSure is a complementary product to its existing surgical product portfolio.

The Company concluded that the acquisition of Interlace did not represent a material business combination, and therefore, no pro forma financial information has been provided herein. Subsequent to the acquisition date, the Company s results of operations include the results of Interlace. The Company accounted for the Interlace acquisition as a purchase of a business under ASC 805.

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The purchase price was comprised of $126.8 million in cash (Initial Consideration), which was net of certain adjustments, plus two annual contingent payments up to a maximum of an additional $225.0 million in cash. In addition to the Initial Consideration, $2.1 million was paid to certain employees upon the completion of three and six months of service from the date of acquisition. Since these payments were contingent on future employment, they were recognized as compensation expense in fiscal 2011.

The agreement includes an indemnification provision that provides for the reimbursement of a portion of legal expenses in defense of the Interlace intellectual property. The Company has the right to collect certain amounts set aside in escrow from the Initial Consideration and, as applicable, offset contingent consideration payments of qualifying legal costs.

The contingent payments are based on a multiple of incremental revenue growth during a two-year period following the completion of the acquisition. Pursuant to ASC 805, the Company recorded its estimate of the fair value of the contingent consideration liability based on future revenue projections of the Interlace business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 15.6%. The discount rate is based on the weighted-average cost of capital of the acquired business plus a credit risk premium for non-performance risk related to the liability pursuant to ASC 820. This analysis resulted in an initial contingent consideration liability of $86.6 million, which will be adjusted periodically as a component of operating expenses based on changes in fair value of the liability driven by the accretion of the liability for the time value of money and changes in the assumptions pertaining to the achievement of the defined revenue growth milestones. This fair value measurement was based on significant inputs not observable in the market and thus represented a Level 3 measurement as defined in ASC 820. As of September 24, 2011, there were no significant changes in the estimated outcomes for the contingent consideration recognized or the discount rate used to determine the fair value. In connection with updating the fair value calculation at September 24, 2011, the Company recorded charges of $6.3 million to record the liability at its fair value of $92.9 million.

The Company did not issue any equity awards in connection with this acquisition. The Company incurred third-party transaction costs of $0.4 million, which were expensed within general and administrative expenses in fiscal 2011.

The purchase price was as follows:

Cash	$ 126,798
Contingent consideration	86,600
Total purchase price	$ 213,398

The allocation of the purchase price was based on preliminary estimates of the fair value of assets acquired and liabilities assumed as of January 6, 2011. The Company is continuing to obtain information pertaining to tax assets and liabilities. The components and allocation of the purchase price consists of the following approximate amounts:

Cash	$ 9,070
Inventory, including fair value adjustments	1,795
Other tangible assets	1,291
Accounts payable and accrued expenses	(1,988)
Developed technology	158,741
Trade names	1,750

Deferred taxes, net	(45,540)
Goodwill	88,279
Purchase Price	$ 213,398

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As part of the purchase price allocation, the Company determined that the separately identifiable intangible assets were developed technology and trade names related to the MyoSure product name. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted at 12.7%. Developed technology represented currently marketable Interlace products that the Company will continue to sell as well as utilize to enhance and incorporate into the Company s existing products. In determining the allocation of the purchase price to existing technology, consideration was only given to products that had been approved by the FDA. Based on the early stage of other projects and an insignificant allocation of resources to those projects, the Company concluded that there were no in-process projects of a material nature.

Developed technology and trade names are being amortized over 15 years and 13 years, respectively.

The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

Beijing Healthcome Technology Company, Ltd.

On July 19, 2011, the Company completed its acquisition of 100% of the equity in Beijing Healthcome Technology Company, Ltd. (Healthcome), a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China. Healthcome manufactures analog mammography products targeted to lower tier hospital segments in China. Additionally, Healthcome had been collaborating with the Company s research and development team to integrate its DirectRay digital detector with the Healthcome mammography platform. This acquisition provides the Company with manufacturing capability in China and additional access to the Chinese markets. The purchase price was $9.8 million in cash, subject to adjustment, which is estimated to include a working capital reduction of $1.7 million. In addition, the Company is obligated to make future payments to the shareholders, who remain employed, up to an additional $7.1 million over three years. Since these payments are contingent on future employment, they will be recognized as compensation expense ratably over the respective service periods. The Company has recorded compensation expense of $0.3 million in fiscal 2011.

The Company accounted for the Healthcome acquisition as a purchase of a business under ASC 805. Subsequent to the acquisition date, the Company s results of operations include the results of Healthcome, which is included within the Company s Breast Health reporting segment.

As part of the preliminary purchase price allocation, the Company determined that the separately identifiable intangible assets were developed technology of $2.8 million, in-process research and development of $0.8 million, and trade names of $0.2 million. The Company is continuing to obtain information to complete its valuation of intangible assets, as well as to determine the acquired assets and liabilities, including tax assets and liabilities. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted using rates ranging from 26% to 29%. Developed technology and trade names will be amortized over their useful lives of 13 and 7 years, respectively. The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired of $5.8 million was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

Fiscal 2010 Acquisition:

Sentinelle Medical Inc.

On August 5, 2010, the Company completed its acquisition of 100% of the equity interests in Sentinelle Medical Inc. (Sentinelle Medical), a privately-held company located in Toronto, Canada, pursuant to a definitive agreement dated July 6, 2010. Sentinelle Medical develops, manufactures and markets magnetic resonance imaging (MRI) breast coils, tables and visualization software. Sentinelle Medical is dedicated to developing advanced imaging technologies used in high-field strength MRI systems. Sentinelle Medical s products enhanced and broadened the Company s portfolio of product offerings in the areas of breast cancer detection and intervention.

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The Company concluded that the acquisition of Sentinelle Medical did not represent a material business combination, and therefore, no pro forma financial information has been provided herein. Subsequent to the acquisition date, the Company s results of operations include the results of Sentinelle Medical, which is included within the Company s Breast Health reporting segment. The Company accounted for the Sentinelle Medical acquisition as a purchase of a business under ASC 805.

The purchase price was comprised of an $84.8 million cash payment, which was net of certain adjustments, plus three contingent payments up to a maximum of an additional $250.0 million in cash. The contingent payments are based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition as follows: six months after acquisition, 12 months after acquisition, and 24 months after acquisition. Pursuant to ASC 805, the Company recorded its estimate of the fair value of the contingent consideration liability based on future revenue projections of the Sentinelle Medical business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 16.5%. The discount rate is based on the weighted-average cost of capital of the acquired business plus a credit risk premium for non-performance risk related to the liability pursuant to ASC 820. This analysis resulted in an initial contingent consideration liability of $29.5 million, which will be adjusted periodically as a component of operating expenses based on changes in the fair value of the liability driven by the accretion of the liability for the time value of money and changes in the assumptions pertaining to the achievement of the defined revenue growth milestones. This fair value measurement was based on significant inputs not observable in the market and thus represented a Level 3 measurement as defined in ASC 820.

During each quarter in fiscal 2011, the Company has re-evaluated its assumptions and updated the revenue and probability assumptions for future earn-out periods and lowered its projections. As a result of these adjustments, which were partially offset by the accretion of the liability, and using a current discount rate of approximately 17.0%, the Company recorded a reversal of expense of $14.3 million in fiscal 2011 to record the contingent consideration liability at fair value. In addition, during the second quarter of fiscal 2011, the first earn-out period ended, and the Company adjusted the fair value of the contingent consideration liability for actual results during the earn-out period. This payment of $4.3 million was made in the third quarter of fiscal 2011. At September 24, 2011, the fair value of the liability is $10.9 million.

The Company did not issue any equity awards in connection with this acquisition. The Company incurred third-party transaction costs of $1.2 million, which were expensed within general and administrative expenses in fiscal 2010.

The purchase price was as follows:

Cash	$ 84,751
Contingent consideration	29,500
Total purchase price	$ 114,251

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The allocation of the purchase price was based on estimates of the fair value of assets acquired and liabilities assumed as of August 5, 2010. The components and allocation of the purchase price consisted of the following:

Cash	$ 429
Inventory, including fair value adjustments	9,899
Other tangible assets	7,247
Accounts payable and accrued expenses	(6,304)
Deferred revenue, including fair value adjustments	(2,056)
Developed technology	60,900
In-process research and development	4,800
Trade names	1,600
Non-compete agreements	300
Deferred taxes, net	(11,181)
Goodwill	48,617
Purchase Price	$ 114,251

As part of the purchase price allocation, the Company determined that the separately identifiable intangible assets were developed technology, in-process research and development, trade names and non-compete agreements. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted using rates of 15.0% to 16.0%. Developed technology represented currently marketable purchased products that the Company will continue to sell as well as utilize to enhance and incorporate into the Company s existing products. In determining the allocation of the purchase price to existing technology, consideration was only given to products that had been approved by the FDA. The trade names related to both the Sentinelle Medical name and certain product names.

The amount allocated to acquired in-process research and development represented the estimated fair value of in-process projects based on risk-adjusted cash flows utilizing a discount rate of 17.0%. These in-process projects had not yet reached technological feasibility and had no future alternative uses as of the date of the acquisition. The primary basis for determining the technological feasibility of these projects was obtaining regulatory approval to market the underlying products. The acquired in-process research and development assets are not subject to amortization until such time the projects are complete, at which time they will be amortized over their estimated remaining useful lives ranging from 10 to 20 years. These projects related to a prostate MRI coil and certain software. The Company received FDA approval for both projects during fiscal 2011 and began to amortize them over their estimated useful lives.

The developed technology assets are being amortized over a weighted average life of approximately 19 years, and trade names are being amortized over a weighted average life of approximately 9 years. Non-compete agreements are being amortized over 3 years.

The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

4. Sale of Makena

On January 16, 2008, the Company entered into a definitive agreement to sell full world-wide rights of its Makena (formerly Gestiva) pharmaceutical product to K-V Pharmaceutical Company (KV) upon FDA approval of the then pending Makena new drug application for $82.0

million. The Company had received $9.5 million of this amount, which had been recorded as a deferred gain, and the remainder was due upon FDA approval. Under this agreement, either party had the right to terminate the agreement if FDA approval was not obtained by February 19, 2010. On January 8, 2010, the parties executed an amendment (First Amendment) to the agreement eliminating the date by which FDA approval must be received and extending the term indefinitely.

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In consideration of executing the First Amendment, the sale price was increased to $199.5 million. The Company received $70.0 million upon the signing of the First Amendment, which was recorded as a deferred gain, and was due to receive an additional $25.0 million upon FDA approval of the product and an additional $95.0 million over a nine-month period beginning one year following FDA approval. On February 3, 2011, the parties executed a second amendment (Second Amendment) to the agreement adjusting the payment provisions under the First Amendment so that upon FDA approval the Company would be due $12.5 million, another $12.5 million one year after approval, and the remaining $95.0 million would be due over an 18 to 30 month period depending on which one of two payment options KV selects. In addition, KV will owe the Company a 5% royalty on sales for certain time periods determined based upon the payment option selected by KV.

Under the arrangement, the Company had been continuing its efforts to obtain FDA approval of Makena. All costs incurred in these efforts were reimbursed by KV and recorded as a credit against research and development expenses. Such reimbursed costs were immaterial to the Company s consolidated financial statements. On February 3, 2011, the Company received FDA approval of Makena, and subject to a right of reversion for failure to make future payments, all rights to Makena were transferred to KV. The Company received $12.5 million, and including the $79.5 million previously received, the Company recorded a gain on the sale of intellectual property, net of the write-off of certain assets, of $84.5 million in the second quarter of fiscal 2011. Due to uncertainty regarding collection, any amounts to be received in the future from KV have not been recorded in the Company s consolidated financial statements, and as the Company receives the amounts owed, the payments will be recorded as a gain within operating expenses in the Consolidated Statement of Operations in the period received.

5. Borrowings and Credit Arrangements

The Company had total debt with a carrying value of $1.49 billion and $1.45 billion at September 24, 2011 and September 25, 2010, respectively, which consisted principally of Convertible Notes (principal of $1.725 billion). The Company has recorded the Convertible Notes net of the unamortized debt discount as required by U.S. generally accepted accounting principles.

Convertible Notes

Original Convertible Notes. On December 10, 2007, the Company issued and sold $1.725 billion, at par, of 2.00% Convertible Senior Notes due 2037 (the Original Notes). Net proceeds from the offering were $1.69 billion, after deducting the underwriters discounts and offering expenses, and were used to repay certain of the Company s outstanding senior secured indebtedness incurred in connection with the merger with Cytyc in fiscal 2008. On November 18, 2010, the Company entered into separate, privately-negotiated exchange agreements under which it retired $450.0 million in aggregate principal of its Original Notes for $450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037 (Exchange Notes). Following these transactions, $1.275 billion in principal amount of the Original Notes remained outstanding. In connection with this exchange transaction, the Company recorded a loss on extinguishment of debt of $29.9 million in its Consolidated Statements of Operations in the first quarter of fiscal 2011.

Holders may require the Company to repurchase the Original Notes on December 13, 2013, and each of December 15, 2017, 2022, 2027 and 2032 or upon a fundamental change, as defined, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest. The Company may redeem any of the Original Notes beginning December 18, 2013, by giving holders at least 30 days notice. The Company may redeem the Original Notes either in whole or in part at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest, including contingent interest and liquidated damages, if any, to, but excluding, the redemption date.

The Original Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on June 15 and December 15 of each year, beginning June 15, 2008 and ending on December 15, 2013. The Original Notes will accrete principal from December 15, 2013 at a rate that provides

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holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing December 15, 2013, the Company will pay contingent interest during any six month interest period to the holders of Original Notes if the trading price , as defined, of the Original Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the Original Notes. The holders of the Original Notes may convert the notes into shares of the Company s common stock at a conversion price of approximately $38.60 per share, subject to adjustment, prior to the close of business on September 15, 2037 under any of the following circumstances: (1) during any calendar quarter if the last reported sale price of the Company s common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of the Company s common stock and the conversion rate on each such day; (3) if the notes have been called for redemption; or (4) upon the occurrence of specified corporate events. None of these triggering events had occurred as of September 24, 2011.

In lieu of delivery of shares of the Company s common stock in satisfaction of the Company s obligation upon conversion of the Original Notes, the Company may elect to deliver cash or a combination of cash and shares of its common stock. If the Company elects to satisfy its conversion obligation in a combination of cash and shares of the Company s common stock, the Company is required to deliver up to a specified dollar amount of cash per $1,000 original principal amount of Original Notes, and will settle the remainder of its conversion obligation in shares of its common stock. It is the Company s current intent and policy to settle any conversion of the Original Notes as if the Company had elected to make the net share settlement election.

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

Exchange Convertible Notes. On November 18, 2010, pursuant to separate, privately-negotiated exchange agreements, the Company retired $450.0 million in aggregate principal of its Original Notes for $450.0 million in aggregate principal of Exchange Notes.

Holders may require the Company to repurchase the Exchange Notes on December 15, 2016, and on each of December 15, 2020, December 15, 2025, December 13, 2030 and December 14, 2035 or upon a fundamental change, as defined in the Second Supplemental Indenture, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest. The Company may redeem any of the notes beginning December 19, 2016, by giving holders at least 30 days notice. The Company may redeem the Exchange Notes either in whole or in part at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest, including contingent interest and liquidated damages, if any, to, but excluding, the redemption date.

The Exchange Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on June 15 and December 15 of each year, beginning December 15, 2010, and ending on December 15, 2016 and will accrete principal from December 15, 2016 at a rate that provides holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing December 15, 2016, the Company will pay contingent interest during any six month interest period to the holders of Exchange Notes if the trading price , as defined, of the Exchange Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the Exchange Notes. The holders of the Exchange Notes may convert the Exchange Notes into shares of the Company s common stock at a conversion price of approximately $23.03 per share, subject to adjustment, prior to the close of business on September 15, 2037 under any of the following circumstances: (1) during any calendar quarter if the last reported sale price of the Company s common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on

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the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of the Company s common stock and the conversion rate on each such day; (3) if the Exchange Notes have been called for redemption; or (4) upon the occurrence of specified corporate events. None of these triggering events had occurred as of September 24, 2011.

In lieu of delivery of shares of the Company s common stock in satisfaction of the Company s obligation upon conversion of the Exchange Notes, the Company may elect to deliver cash or a combination of cash and shares of its common stock. If the Company elects to satisfy its conversion obligation in a combination of cash and shares of the Company s common stock, the Company is required to deliver up to a specified dollar amount of cash per $1,000 original principal amount of Exchange Notes, and will settle the remainder of its conversion obligation in shares of its common stock. It is the Company s current intent and policy to settle any conversion of the Exchange Notes as if the Company had elected to make the net share settlement election.

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

Accounting for the Convertible Notes

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1)(codified within ASC 470, *Debt*). This accounting standard applies to certain convertible debt instruments that may be settled in cash, or partially in cash, upon conversion. The liability and equity components of convertible debt instruments within the scope of this accounting standard must be separately accounted for in a manner that reflects the entity s nonconvertible debt borrowing rate when interest expense is subsequently recognized. The excess of the principal amount of the debt over the amount allocated to the liability component is recognized as the value of the embedded conversion feature within additional-paid-in capital in stockholders equity and amortized to interest expense using the effective interest method.

On September 27, 2009 (the first day of fiscal 2010), the Company adopted this accounting standard, which is applicable to its Convertible Notes, which can be settled or partially settled in cash. Accordingly, the Company accounted for the liability and equity components of its Original Notes separately to reflect its nonconvertible debt borrowing rate. The Company estimated the fair value of the Original Notes without the conversion feature as of the date of issuance (liability component). The estimated fair value of the liability component of $1.256 billion was determined using a discounted cash flow technique. Key inputs used to estimate the fair value of the liability component included the Company s estimated nonconvertible debt borrowing rate as of December 10, 2007 (the date the Convertible Notes were issued), the amount and timing of cash flows, and the expected life of the Convertible Notes. The estimated effective interest rate of 7.62% was estimated by comparing other companies debt issuances that had features similar to the Company s debt excluding the conversion feature and who had similar credit ratings during the same annual period as the Company.

The excess of the gross proceeds received over the estimated fair value of the liability component totaling $468.9 million was allocated to the conversion feature (equity component) as an increase to capital in excess of par value with a corresponding offset recognized as a discount to reduce the net carrying value of the Convertible Notes. The discount, after adjustment for the exchange of Convertible Notes as discussed below, is being amortized to interest expense over a six-year period ending December 18, 2013 (the expected life of the liability component) using the effective interest method. In addition, third-party transaction costs are required to be allocated to the liability and equity components based on their relative values. As such, a portion of the deferred financing costs were allocated to the equity component and recorded as a reduction to capital in excess of par value.

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As of September 25, 2010, the carrying amount of the Original Notes and related equity component (recorded in capital in excess of par value, net of deferred taxes) consisted of the following:

Convertible notes principal amount	$ 1,725,000
Unamortized discount	(277,947)
Net carrying amount	$ 1,447,053
Equity component, net of taxes	$ 283,638

As noted above, on November 18, 2010, the Company executed separate, privately-negotiated exchange agreements, and the Company retired $450.0 million in aggregate principal of its Original Notes for $450.0 million in aggregate principal of Exchange Notes. The Company accounted for this retirement under the derecognition provisions of subtopic ASC 470-20-40, which requires the allocation of the fair value of the consideration transferred (i.e., the Exchange Notes) between the liability and equity components of the original instrument to determine the gain or loss on the transaction. In connection with this transaction, the Company recorded a loss on extinguishment of debt of $29.9 million, which is comprised of the loss on the debt itself of $26.0 million and the write-off of the pro-rata amount of debt issuance costs of $3.9 million allocated to the notes retired. The loss on the debt itself is calculated as the difference between the fair value of the liability component of the Original Notes amount retired immediately before the exchange and its related carrying value immediately before the exchange. The fair value of the liability component was calculated similar to the description above for initially recording the Original Notes under FSP APB 14-1, and the Company used an effective interest rate of 5.46%, representing the estimated nonconvertible debt borrowing rate with a three year maturity at the measurement date. In addition, under this accounting standard, a portion of the fair value of the consideration transferred is allocated to the reacquisition of the equity component, which is the difference between the fair value of the consideration transferred and the fair value of the liability component immediately before the exchange. As a result, $39.9 million was allocated to the reacquisition of the equity component of the original instrument, which is recorded net of deferred taxes within capital in excess of par value.

Since the Exchange Notes have the same characteristics as the Original Notes and can be settled in cash or a combination of cash and shares of common stock (i.e., partial settlement), the Company is required to account for the liability and equity components of its Exchange Notes separately to reflect its nonconvertible debt borrowing rate. The Company estimated the fair value of the Exchange Notes liability component to be $349.0 million using a discounted cash flow technique. Key inputs used to estimate the fair value of the liability component included the Company s estimated nonconvertible debt borrowing rate as of November 18, 2010 (the date the Convertible Notes were issued), the amount and timing of cash flows, and the expected life of the Exchange Notes. The Company used an estimated effective interest rate of 6.52%.

The excess of the fair value transferred over the estimated fair value of the liability component totaling $97.3 million was allocated to the conversion feature as an increase to capital in excess of par value with a corresponding offset recognized as a discount to reduce the net carrying value of the Exchange Notes. As a result of the fair value of the Exchange Notes being lower than the Exchange Notes principal value, there is an additional discount on the Exchange Notes of $3.7 million at the measurement date. The total discount is being amortized to interest expense over a six-year period ending December 15, 2016 (the expected life of the liability component) using the effective interest method. In addition, third-party transaction costs have been allocated to the liability and equity components based on the relative values of these components.

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As of September 24, 2011, the Convertible Notes (both the Original Notes and Exchange Notes) and related equity components (recorded in capital in excess of par value, net of deferred taxes) consisted of the following:

Original Notes principal amount	$ 1,275,000
Unamortized discount	(147,287)
Net carrying amount	$ 1,127,713
Equity component, net of taxes	$ 259,000
Exchange Notes principal amount	$ 450,000
Unamortized discount	(89,133)
Net carrying amount	$ 360,867
Equity component, net of taxes	$ 60,054

Interest expense under the Convertible Notes is as follows:

	Years ended		
	September 24, 2011	September 25, 2010	September 26, 2009
Amortization of debt discount	$ 72,908	$ 73,130	$ 67,673
Amortization of deferred financing costs	3,906	4,092	3,786
Non-cash interest expense	76,814	77,222	71,459
2.00% accrued interest	34,427	34,500	34,269
	$ 111,241	$ 111,722	$ 105,728

If the Company fails to comply with the reporting obligations contained in the Convertible Notes agreements, the sole remedy of the holders of the Convertible Notes for the first 90 days following such event of default consists exclusively of the right to receive an extension fee in an amount equal to 0.25% of the accreted principal amount of the Convertible Notes. Based on the Company s evaluation of the Convertible Notes in accordance with ASC 815, *Derivatives and Hedging*, Subtopic 40, *Contracts in Entity s Own Equity*, the Company determined that the Convertible Notes contain a single embedded derivative, comprising both the contingent interest feature and the filing failure penalty payment, requiring bifurcation as the features are not clearly and closely related to the host instrument. The Company has determined that the value of this embedded derivative was nominal as of September 24, 2011 and September 25, 2010.

As of September 24, 2011, upon conversion, including the potential premium that could be payable on a fundamental change (as defined), the Company would issue a maximum of approximately 68.6 million common shares to the Convertible Note holders.

(b) Credit Agreement

On October 22, 2007, the Company and certain of its domestic subsidiaries entered into a senior secured credit agreement (the Credit Agreement) with Goldman Sachs Credit Partners L.P. and certain other lenders, (collectively, the Lenders). Pursuant to the terms and conditions of the Credit Agreement, the Lenders committed to provide senior secured financing in an aggregate amount of up to $2.55 billion. As of the closing of the merger with Cytyc, the Company borrowed $2.35 billion under the credit facilities. The Company used the proceeds from the credit facilities to pay the cash consideration of the merger with Cytyc, and to pay fees, commissions and expenses incurred by the Company in connection with the merger with Cytyc and the Credit Agreement. In addition, the Company used the proceeds of the credit facilities, together with the Company s available cash, to pay the cash due upon conversion of Cytyc s 2.25% Senior Convertible Notes due 2024 that were outstanding after the closing of the merger with Cytyc.

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In connection with the acquisition of Third Wave, on July 17, 2008, the Company entered into an amended and restated credit agreement with certain of the Lenders (the Amended Credit Agreement). Pursuant to the terms and conditions of the Amended Credit Agreement, the Lenders committed to provide senior secured financing in an aggregate amount of up to $800.0 million. The credit facilities under the Amended Credit Agreement consisted of $400.0 million senior secured tranche A term loan (Term Loan A); $200.0 million senior secured tranche B term loan (Term Loan B); $200.0 million senior secured revolving credit facility (the Revolving Facility). In order to complete the acquisition of Third Wave, the Company borrowed $540.0 million on July 17, 2008, consisting of $400.0 million under Term Loan A and $140.0 million under Term Loan B. The Company never borrowed any amounts under the Revolving Facility. In the third quarter of fiscal 2010, the Company completed its obligation to pay off the loans, which was prior to the maturity dates, and terminated the Amended Credit Agreement.

Borrowings outstanding under the Amended Credit Agreement in fiscal 2010 and 2009 had a weighted average interest rate of 2.8% and 3.81%, respectively. Interest expense under the Amended Credit Agreement totaled $8.2 million and $23.9 million, respectively, in fiscal 2010 and 2009, which includes non-cash interest expense of $6.4 million and $10.8 million, respectively, related to the amortization of the deferred financing costs.

Interest expense under the Amended Credit Agreement for the Revolving Facility totaled $3.6 million and $1.9 million in fiscal 2010 and 2009, respectively, consisting of commitment fees on the unused portion of this facility and non-cash interest expense of $3.0 million and $1.0 million, respectively, related to the amortization of deferred financing costs. Included in the non-cash interest expense for fiscal 2010 was a $2.2 million write-off of the remaining deferred financing costs due to the termination of the Revolving Facility.

6. Fair Value Measurements

The Company applies the provisions of ASC 820, *Fair Value Measurements and Disclosures*, for its financial assets and liabilities that are re-measured and reported at fair value each reporting period and its nonfinancial assets and liabilities that are re-measured and reported at fair value on a non-recurring basis. Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability.

Fair Value Hierarchy

ASC 820 establishes a three-level valuation hierarchy for disclosure of fair value measurements. Financial assets and liabilities are categorized within the valuation hierarchy based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

Level 1 Inputs to the valuation methodology are quoted market prices for identical assets or liabilities.

Level 2 Inputs to the valuation methodology are other observable inputs, including quoted market prices for similar assets or liabilities and market-corroborated inputs.

Level 3 Inputs to the valuation methodology are unobservable inputs based on management s best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk.

Assets/Liabilities Measured and Recorded at Fair Value on a Recurring Basis

As of September 24, 2011 and September 25, 2010, the Company s financial assets that are re-measured at fair value on a recurring basis included $0.3 million in money market mutual funds in both periods that are classified as cash and cash equivalents in the Consolidated Balance Sheets. Money market mutual funds are classified within Level 1 of the fair value hierarchy and are valued using quoted market prices for identical assets. The Company has a payment obligation under its DCP to the participants of the DCP. This liability is recorded at fair value based on the underlying value of certain hypothetical investments as designated by each participant for their benefit. Since the value of the DCP obligation is based on market prices, the liability is

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classified within Level 1. In addition, the Company has contingent consideration liabilities related to its acquisitions that it records at fair value. The fair values of these liabilities are based on Level 3 inputs and are discussed in Note 3.

Assets and liabilities measured at fair value on a recurring basis consisted of the following at September 24, 2011:

		Fair Value at Reporting Date Using		
	Balance as of September 24, 2011	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 314	$ 314	$	$
Total	$ 314	$ 314	$	$
Liabilities:				
DCP liability	$ 17,168	$ 17,168	$	$
Contingent consideration	103,790			103,790
Total	$ 120,958	$ 17,168	$	$ 103,790

Changes in the fair value of recurring fair value measurements, which solely consisted of contingent consideration liabilities, using significant unobservable inputs (Level 3) during the year ended September 24, 2011 were as follows:

Balance at September 25, 2010	$ 29,500
Contingent consideration liabilities recorded at fair value at acquisition	86,600
Fair value adjustments recorded to operating expenses	(8,016)
Payment of contingent consideration liabilities recorded at fair value	(4,294)
Balance at September 24, 2011	$ 103,790

Assets Measured and Recorded at Fair Value on a Nonrecurring Basis

The Company remeasures the fair value of certain assets and liabilities upon the occurrence of certain events. Such assets comprise cost-method equity investments and long-lived assets, including property and equipment, intangible assets and goodwill. During fiscal 2010, the Company recorded impairment charges of $143.5 million and $76.7 million to adjust intangible assets and goodwill, respectively, related to its MammoSite reporting unit to their estimated fair values. These adjustments fall within Level 3 of the fair value hierarchy due to the use of significant unobservable inputs to determine fair value. The fair value measurements using a discounted cash flow technique, and the amount and timing of future cash flows within the analysis were based on the Company s most recent operational budgets, long-range strategic plans and other estimates at the time such remeasurement was made.

The Company holds certain cost-method equity investments in non-publicly traded securities aggregating $4.6 million and $7.0 million at September 24, 2011 and September 25, 2010, respectively, which are included in other long-term assets on the Company s Consolidated Balance Sheets. These investments are generally carried at cost. As the inputs utilized for the Company s periodic impairment assessment are not based on observable market data, these cost method investments are classified within Level 3 of the fair value hierarchy. To determine the fair value of these investments, the Company uses all available financial information related to the entities, including information based on recent or pending third-party equity investments in these entities. In certain instances, a cost method investment s fair value is not estimated as there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment and to do so would be impractical. During fiscal 2011, 2010 and 2009, the Company recorded other-than-temporary impairment charges of $2.4 million, $1.1 million and $2.2 million, respectively, related to certain of its cost-method equity investments to adjust their carrying amounts to fair value.

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The following chart depicts the level of inputs within the fair value hierarchy used to estimate the fair value of intangible assets, goodwill and cost-method equity investment measured on a nonrecurring basis for which the Company recorded impairment charges in fiscal 2011 and 2010:

		Fair Value Measurements Using			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Gains (Losses)
Fiscal 2011:					
Cost-method equity investments	$ 345			$ 345	$ (2,445)
Fiscal 2010:					
Intangible assets	$ 24,290			$ 24,290	$ (143,467)
Goodwill	5,826			5,826	(76,723)
Cost-method equity investment					(1,100)
					$ (221,290)

The above fair value amounts represent only those individual assets remeasured and not the consolidated balances. Refer to Note 5 for disclosure of the nonrecurring fair value measurement related to the loss on extinguishment of debt recorded in the first quarter of fiscal 2011.

Disclosure of Fair Value of Financial Instruments

The Company s financial instruments mainly consist of cash and cash equivalents, accounts receivable, cost-method equity investments, insurance contracts and related DCP liability, accounts payable and debt obligations. The carrying amounts of the Company s cash equivalents, accounts receivable and accounts payable approximate their fair value due to the short-term nature of these instruments. The carrying amount of the insurance contracts are recorded at the cash surrender value, as required by U.S. generally accepted accounting principles, which approximates fair value, and the related DCP liability is recorded at fair value. The Company believes the carrying amounts of its cost-method investments approximate fair value.

The Company had $1.49 billion and $1.45 billion of Convertible Notes recorded (See Note 5) as of September 24, 2011 and September 25, 2010, respectively. The aggregate principal amount of the Convertible Notes at both periods was $1.725 billion. On November 18, 2010, the Company entered into separate, privately-negotiated exchange agreements under which it retired $450.0 million in aggregate principal of its Original Notes for $450.0 million in aggregate principal of Exchange Senior Notes. Following these transactions, $1.275 billion in principal amount of the Original Notes remained outstanding. The fair value of the remaining Original Notes and the Exchange Notes as of September 24, 2011 was approximately $1.20 billion and $468.7 million, respectively. The aggregate fair value of the Company s Convertible Notes was approximately $1.62 billion as of September 25, 2010. Fair value is based on the trading prices of the respective notes at the dates noted.

7. Pension and Other Employee Benefits

The Company has certain defined benefit pension plans covering the employees of its AEG German subsidiary (the Pension Benefits). As of September 24, 2011 and September 25, 2010, the Company s pension liability is $8.1 million and $9.1 million, respectively, which is primarily recorded as a component of long-term liabilities in the Consolidated Balance Sheets. Under German law, there are no rules governing investment

or statutory supervision of the pension plan. As such, there is no minimum funding requirement imposed on employers. Pension benefits are safeguarded by the Pension Guaranty Fund, a form of compulsory reinsurance that guarantees an employee will receive vested pension benefits in the event of insolvency.

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The tables below provide a reconciliation of benefit obligations, plan assets, funded status, and related actuarial assumptions of the Company s German Pension Benefits.

	Years ended		
Change in Benefit Obligation	**September 24, 2011**	**September 25, 2010**	**September 26, 2009**
Benefit obligation at beginning of year	$ (9,093)	$ (6,736)	$ (7,323)
Service cost			
Interest cost	(389)	(401)	(469)
Plan participants contributions			
Actuarial gain (loss)	1,092	(2,814)	764
Foreign exchange	(5)	541	(28)
Benefits paid	331	317	320
Benefit obligation at end of year	(8,064)	(9,093)	(6,736)
Plan assets			
Funded status	$ (8,064)	$ (9,093)	$ (6,736)

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

	Years ended		
Components of Net Periodic Benefit Cost	**September 24, 2011**	**September 25, 2010**	**September 26, 2009**
Service cost	$	$	$
Interest cost	389	401	469
Expected return on plan assets			
Amortization of prior service cost			
Recognized net actuarial gain		(217)	(169)
Net periodic benefit cost	$ 389	$ 184	$ 300

Weighted-Average Net Periodic Benefit Cost Assumptions	**2011**	**2010**	**2009**
Discount rate	5.20%	4.35%	6.6%
Expected return on plan assets	0%	0%	0%
Rate of compensation increase	0%	0%	0%

The projected benefit obligation for the German Pension Benefits plans with projected benefit obligations in excess of plan assets was $8.1 million and $9.1 million at September 24, 2011 and September 25, 2010, respectively, and the accumulated benefit obligation for the German Pension Benefits plans was $8.1 million and $9.1 million at September 24, 2011 and September 25, 2010, respectively.

The Company is also obligated to pay long-term service award benefits. The projected benefit obligation for long-term service awards was $0.6 million and $0.7 million at September 24, 2011 and September 25, 2010, respectively.

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The table below reflects the total Pension Benefits expected to be paid as of September 24, 2011 from the plans.

2012	$ 349
2013	369
2014	391
2015	410
2016	425
2017 to 2021	2,315

The Company also maintains additional contractual pension benefits for its top German executive officers in the form of a defined contribution plan. These contributions were insignificant in fiscal 2011, 2010 and 2009.

8. Income Taxes

The Company s income (loss) before income taxes consisted of the following:

	Years ended		
	September 24, 2011	**September 25, 2010**	**September 26, 2009**
Domestic	$ 235,204	$ (70,750)	$ (2,161,264)
Foreign	(7,818)	15,759	7,134
	$ 227,386	$ (54,991)	$ (2,154,130)

The provision for income taxes consisted of the following:

	Years ended		
	September 24, 2011	**September 25, 2010**	**September 26, 2009**
Federal:			
Current	$ 97,834	$ 105,664	$ 74,311
Deferred	(33,808)	(108,002)	(18,462)
	64,026	(2,338)	55,849
State:			
Current	15,739	18,334	9,804
Deferred	(5,909)	(11,501)	(8,351)
	9,830	6,833	1,453
Foreign:			
Current	4,770	5,550	5,388
Deferred	(8,390)	(2,223)	(178)

	(3,620)	3,327	5,210
	$ 70,236	$ 7,822	$ 62,512

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A reconciliation of income taxes at the U.S. federal statutory rate to the Company s effective tax rate is as follows:

	Years ended		
	September 24, 2011	September 25, 2010	September 26, 2009
Income tax provision at federal statutory rate	35.0%	(35.0)%	(35.0)%
Increase (decrease) in tax resulting from:			
Goodwill impairment		48.7	37.9
Section 199 manufacturing deduction	(4.1)	(11.6)	(0.3)
State income taxes, net of federal benefit	3.6	2.7	0.2
Tax credits	(3.2)	(6.9)	(0.2)
Unrecognized tax benefits	(3.3)	7.2	0.1
Contingent consideration	1.5		
Permanent differences	0.8	3.1	0.1
Executive compensation	(1.1)	6.1	0.1
State law change			(0.1)
Foreign rate differential	0.8	(1.0)	
Change in valuation allowance		(0.6)	0.1
Other	0.9	1.5	
	30.9%	14.2%	2.9%

The Company s effective tax rate for fiscal 2011 was less than the statutory rate primarily due to the reversal of income tax reserves, the Section 199 manufacturing deduction for domestic production activities and U.S. and Canadian research and development tax credits. The reversal of $9.1 million of income tax reserves was due to the closure of the United States Internal Revenue Service (the IRS) federal audit for fiscal years 2007, 2008 and 2009 and the expiration of the statute of limitations in various domestic (federal and state) and foreign jurisdictions.

The effective tax rate for fiscal 2010 was significantly impacted by the goodwill impairment charge recorded in the fourth quarter of fiscal 2010, substantially all of which was not deductible for tax purposes. In addition, the Company recorded provision to return adjustments and additional reserve needs partially offset by the reversal of reserves no longer required. The reserves no longer required principally related to the sale of the Company s manufacturing operation in Shanghai, China in the second quarter of fiscal 2010, and the expiration of the statute of limitations in several jurisdictions. The effective tax rate for fiscal 2009 was significantly impacted by the goodwill impairment charge recorded in the second quarter of fiscal 2009, substantially all of which was not deductible for tax purposes. In addition, the tax provision for fiscal 2009 included a reversal for a charge recorded in fiscal 2008 for approximately $2.3 million related to a clarification in Massachusetts tax law on apportionment for affiliates of manufacturing companies. The Company also recorded an additional $1.3 million in anticipation of losing its tax holiday status due to the closure of its manufacturing facility in Shanghai, China.

The Company accounts for income taxes using the liability method as required by ASC 740. Under this method, deferred income taxes are recognized for the future tax consequences of differences between the tax and financial accounting bases of assets and liabilities at the end of each reporting period. Deferred income taxes are based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized.

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Significant components of the Company s deferred tax assets and liabilities are as follows:

	September 24, 2011	September 25, 2010
Deferred tax assets		
Net operating loss carryforwards	$ 56,641	$ 76,365
Nondeductible accruals	17,767	8,776
Nondeductible reserves	8,400	9,038
Stock-based compensation	23,826	26,236
Research and other credits	13,207	12,141
Convertible notes issuance costs	1,283	1,410
Deferred gain		29,396
Nonqualified deferred compensation plan	7,324	6,093
Other temporary differences	4,267	4,500
	132,715	173,955
Less: valuation allowance	(13,930)	(16,798)
	$ 118,785	$ 157,157
Deferred tax liabilities		
Depreciation and amortization	$ (771,504)	$ (782,770)
Debt discount on convertible notes	(100,538)	(106,410)
Original issue discount	(131,732)	(146,101)
Deferral on convertible notes exchange	(26,323)	
Investment in subsidiary	(6,507)	(4,679)
	$ (1,036,604)	$ (1,039,960)
	$ (917,819)	$ (882,803)

Under ASC 740, *Income Taxes*, the Company can only recognize a deferred tax asset for the future benefit of its tax loss and credit carryforwards to the extent that it is more likely than not that these assets will be realized. After considering all available positive and negative evidence, the Company has established a valuation allowance against a portion of its remaining deferred tax assets because it is more likely than not that a portion of its tax loss carryforward will not be realized. In determining the realizability of these assets, the Company considered numerous factors, including historical profitability, estimated future taxable income and the industry in which it operates. The valuation allowance decreased $2.9 million in fiscal 2011 from fiscal 2010 primarily due to the expiration of certain federal and state net operating losses.

During fiscal years 2011, 2010 and 2009, the Company recorded reductions of $2.0 million, $1.1 million and $1.1 million, respectively, to goodwill related to the tax benefit of stock options exercised that had been assumed in acquisitions prior to the adoption of ASC 805.

As of September 24, 2011, the Company had gross federal, state and foreign net operating losses of $79.3 million, $4.5 million and $48.4 million respectively, and federal, state and foreign credit carryforwards of $4.5 million, $8.6 million and $2.7 million respectively, that it believes are more likely than not that they will be realized. The federal and state net operating losses exclude $5.8 million and $16.9 million, respectively, of net operating losses, which the Company believes will expire unutilized. The following table summarizes the expiration periods of the net operating losses and credit carryforwards:

	Period of Expiration					
	2012-2017	2018-2021	2023-2027	2028-2032	No expiration	Total
Federal net operating losses	$ 4,800	$ 25,488	$ 43,521	$ 5,504		$ 79,313
State net operating losses	268	9	1,122	3,123		4,522
Foreign net operating losses			885	35,122	12,395	48,402
Federal tax credits		2,596	1,665	254		4,515
Canadian tax credits				2,691		2,691
CA tax credits					1,958	1,958
CT tax credits	136	1,454	207		1,464	3,261
MA tax credits		600	1,238		506	2,344
IN tax credits	394	646				1,040

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The Company had gross unrecognized tax benefits, including interest, of $30.6 million as of September 24, 2011 and $33.5 million as of September 25, 2010. At September 24, 2011, $30.6 million represents the amount of unrecognized tax benefits that, if recognized, would result in a reduction of the Company s effective tax rate. In the next twelve months it is reasonably possible that the Company will reduce the balance of its unrecognized tax benefits by $2.6 million due to the expiration of statute of limitations and settlements with taxing authorities, all of which would reduce the Company s effective tax rate.

Activity of the Company s unrecognized income tax benefits for fiscal 2011 and 2010 are as follows:

	2011	2010
Balance at beginning of fiscal year	$ 31,790	$ 28,073
Tax positions related to current year:		
Additions	2,014	2,364
Reductions		
Tax positions related to prior years:		
Additions related to change in estimate	5,934	3,682
Reductions	(700)	(675)
Payments	(1,182)	(193)
Lapses in statutes of limitations and settlements	(9,162)	(1,461)
Acquired tax positions:		
Additions related to reserves acquired from acquisitions	565	
Balance as of the end of the fiscal year	$ 29,259	$ 31,790

The Company s policy is to recognize accrued interest and penalties related to unrecognized tax benefits and income tax liabilities, when applicable, as part of income tax expense in its Consolidated Statements of Operations. As of September 24, 2011 and September 25, 2010, accrued interest was $1.4 million and $1.7 million, respectively, net of federal benefit. As of September 24, 2011, no penalties have been accrued.

The Company and its subsidiaries are subject to United States federal income tax, as well as income tax in multiple state and foreign jurisdictions. The current tax returns are open for audit through fiscal 2015. The Company had been under audit by the IRS for fiscal years 2007, 2008 and 2009. The IRS concluded its audit and issued its final report for these fiscal years resulting in a $7.6 million payment, substantially all of which had been previously recorded within deferred tax liabilities, to settle the issues raised by the IRS. The Company has a tax holiday in Costa Rica that currently does not materially impact its effective tax rate and is scheduled to expire in 2015.

The Company intends to reinvest, indefinitely, approximately $29.5 million of unremitted foreign earnings. It is not practical to estimate the amount of additional taxes that might be payable upon repatriation of foreign earnings.

9. Stockholders Equity and Stock-Based Compensation

Common Shares Authorization

At the Company s March 11, 2008 Annual Meeting of Stockholders, an increase in the number of authorized shares of common stock from 600 million to 750 million was approved.

Rights Agreement

On April 2, 2008, the Company entered into an Amended and Restated Rights Agreement (the Amended and Restated Rights Agreement) between the Company and American Stock Transfer & Trust Company as Rights Agent (the Rights Agent). The Amended and Restated Rights Agreement amends and restates the Company s rights agreement, dated as of September 17, 2002, as amended on May 21, 2007, between the Company and the Rights Agent.

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On April 2, 2008, the Company effected a two-for-one stock split in the form of a stock dividend to stockholders as of March 21, 2008. Pursuant to the Amended and Restated Rights Agreement, the Company amended the terms of the rights issued and issuable under the agreement (Rights), effective as of April 3, 2008 (after the stock dividend), to reset the Rights such that each share of Common Stock is entitled to receive one Right, to retain the purchase price of each Right at $60 per Right, and to provide that each Right will entitle the holder to purchase one twenty-five thousandth of a share of Series A Junior Participating Preferred Stock (the Series A Preferred Stock). Conforming changes have also been made to the Company s certificate of designation for the Series A Preferred Stock to provide that each share of Series A Preferred Stock carries 25,000 times the dividend, liquidation and voting rights of the Company s Common Stock. Other modifications have also been made in the Amended and Restated Rights Agreement to update the agreement for certain developments, including the recent amendments to the Company s by-laws permitting stockholders to hold and transfer shares of the Company s capital stock in book entry form. The expiration date of the Rights has remained unchanged at January 1, 2013.

Stock-Based Compensation

Equity Compensation Plans

The Company has one share-based compensation plan pursuant to which awards are currently being made the 2008 Equity Incentive Plan. The Company has four share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made i) the 1995 Combination Stock Option Plan; ii) the 1997 Employee Equity Incentive Plan; iii) the 1999 Equity Incentive Plan; and iv) the 2000 Acquisition Equity Incentive Plan.

At the Company s March 11, 2008 Annual Meeting of Stockholders, the Company s 2008 Equity Incentive Plan (the 2008 Equity Plan) was approved. In connection with this approval, the Company s 1999 Second Amended and Restated Equity Incentive Plan was terminated. The purpose of the 2008 Equity Plan is to provide stock options, stock issuances and other equity interests in the Company to employees, officers, directors, consultants and advisors of the Company and its parents and subsidiaries, and any other person who is determined by the Board of Directors to have made (or is expected to make) contributions to the Company. The 2008 Equity Plan is administered by the Board of Directors of the Company, and a total of 20 million shares were reserved for issuance under this plan. As of September 24, 2011, the Company had approximately 8.2 million shares available for future grant under this plan.

The Company assumed certain other plans in connection with the Cytyc and Third Wave acquisitions, and no shares are available for future grant under these plans.

Grant-Date Fair Value

Effective with the adoption of ASC 718, the Company elected to use a binomial lattice model to determine the fair value of its stock options. The Company considers a number of factors to determine the fair value of options including the assistance of an outside valuation advisor. Information pertaining to stock options granted during fiscal 2011, 2010 and 2009 and related assumptions are noted in the following table:

	Years ended		
	September 24, 2011	**September 25, 2010**	**September 26, 2009**

Options granted	2,249	2,858	3,007
Weighted-average exercise price	$ 17.15	$ 15.65	$ 14.43
Weighted-average grant date fair value	$ 6.16	$ 5.87	$ 5.40
Assumptions:			
Risk-free interest rates	1.0%	1.8%	2.0%
Expected life (in years)	4.2	3.9	4.0
Expected volatility	45%	47%	46%
Dividend yield			

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The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. In projecting expected stock price volatility, the Company uses a combination of historical stock price volatility and implied volatility from observable market prices of similar equity instruments. The Company estimated the expected life of stock options based on historical experience using employee exercise and option expiration data.

Stock-Based Compensation Expense

The Company uses the straight-line attribution method to recognize stock-based compensation expense for stock options and restricted stock units (RSU). The vesting term of stock options is generally five years with annual vesting of 20% per year on the anniversary of the grant date, and RSUs generally either cliff vest at the end of three years or vest over four years with annual vesting at 25% per year on the anniversary of the grant date. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. ASC 718 requires forfeitures to be estimated at the time granted and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Based on an analysis of historical forfeitures, the Company has determined a specific forfeiture rate for certain employee groups and has applied forfeiture rates ranging from 0% to 5% as of September 24, 2011 depending on the specific employee group. This analysis is re-evaluated annually and the forfeiture rate will be adjusted as necessary. Ultimately, the actual stock-based compensation expense recognized will only be for those stock options and RSUs that vest.

Stock-based compensation expense in fiscal 2011, 2010 and 2009 is as follows:

	2011	2010	2009
Cost of revenues	$ 4,602	$ 4,332	$ 3,522
Research and development	4,852	4,011	3,960
Selling and marketing	5,954	5,313	5,161
General and administrative	20,064	20,504	20,296
	$ 35,472	$ 34,160	$ 32,939

Stock-based compensation expense related to stock options was $15.2 million, $13.3 million, and $13.8 million in fiscal years 2011, 2010 and 2009, respectively. Stock compensation expense related to RSUs was $20.3 million, $20.9 million, and $19.1 million in fiscal years 2011, 2010 and 2009, respectively. The related tax benefit recorded in the Consolidated Statements of Operations was $14.8 million, $9.9 million and $9.8 million in fiscal years 2011, 2010 and 2009, respectively. At September 24, 2011, there was $30.8 million and $32.2 million of unrecognized compensation expense related to stock options and RSUs, respectively, to be recognized over a weighted average period of 3.0 years and 2.4 years, respectively.

Option Exchange Program

On December 22, 2008, the Board of Directors approved, subject to stockholder approval, a stock option exchange program (the Option Exchange Program). The Option Exchange Program was approved at the Annual Meeting of Stockholders held on March 4, 2009. The Option Exchange Program permitted eligible employees to exchange their outstanding options issued on January 16, 2008 at an exercise price per share of $33.31 for a lesser number of new options (New Options), with such number of New Options issuable upon exchange calculated pursuant to an exchange ratio based on the original exercise price of the surrendered option. The exchange offer expired on April 5, 2009. Pursuant to the Option Exchange Program, the New Options have an exercise price of $14.87, which is 110% of the last reported closing sales price of the

Company s common stock as of the date of the new grant, which was April 5, 2009. The total number of stock options eligible to be exchanged of approximately 784,000 was exchanged for 406,000 New Options.

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On the date of exchange, the estimated fair value of the New Options approximated the estimated fair value of the exchanged stock options calculated immediately prior to the exchange. As such, there is no incremental fair value of the New Options, and the Company will not record additional compensation expense related to the exchange. The Company will continue to recognize the remaining compensation expense related to the exchanged options over the remaining vesting period of the original options. The New Options become exercisable over a period of four years, with 25% vesting on the first anniversary of the date the New Options were granted and 25% vesting on each anniversary thereafter, so long as the option holder continues to be employed by the Company.

Share Based Payment Activity

The following table summarizes all stock option activity under the Company s stock option plans for the year ended September 24, 2011:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at September 25, 2010	15,545	$ 16.70		
Granted	2,249	17.15		
Cancelled/forfeited	(537)	19.89		
Exercised	(1,779)	13.43		$ 12,265
Options outstanding at September 24, 2011	15,478	$ 17.01	4.11	$ 30,455
Options exercisable at September 24, 2011	8,964	$ 16.75	3.37	$ 28,418
Options vested and expected to vest at September 24, 2011 (1)	15,412	$ 17.01	4.11	$ 30,437

(1) This represents the number of vested stock options as of September 24, 2011 plus the unvested outstanding options at September 24, 2011 expected to vest in the future, adjusted for estimated forfeitures.

During fiscal 2010 and 2009, the total intrinsic value of options exercised (i.e., the difference between the market price on the date of exercise and the price paid by the employee to exercise the options) was $7.3 million and $10.5 million, respectively.

A summary of the Company s RSU activity during the year ended September 24, 2011 is presented below:

Non-vested Shares	Number of Shares	Weighted-Average Grant-Date Fair Value
Non-vested at September 25, 2010	3,676	$ 19.90
Granted.	1,236	16.83
Vested	(1,675)	25.76
Forfeited	(125)	16.74

Non-vested at September 24, 2011	3,112	$	15.67

The number of RSUs vested includes shares withheld on behalf of employees to satisfy minimum statutory tax withholding requirements. During fiscal 2011, 2010 and 2009 the total fair value of RSUs vested was $43.2 million, $7.5 million and $5.0 million, respectively.

Employee Stock Purchase Plan

At the Company s March 11, 2008 Annual Meeting of Stockholders, the Company s 2008 Employee Stock Purchase Plan (the ESPP) was approved. The plan meets the criteria set forth in ASC 718 s definition of a non-compensatory plan and does not give rise to stock-based compensation expense. Employees who have

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completed three consecutive months, or two years, whether or not consecutive, of employment with the Company or any of its participating subsidiaries are eligible to participate in the ESPP. The ESPP plan period is semi-annual and allows participants to purchase the Company s common stock at 95% of the closing price of the stock on the last day of the plan period. A total of 400,000 shares may be issued under the ESPP, and at September 24, 2011, 95,000 shares are available for future issuance.

10. Profit Sharing 401(k) Plan

The Company has a qualified profit sharing plan covering substantially all of its employees. Contributions to the plan are at the discretion of the Company s Board of Directors. The Company made contributions of $6.4 million, $5.9 million and $5.7 million for fiscal years 2011, 2010 and 2009, respectively.

11. Nonqualified Deferred Compensation Plan

Effective March 15, 2006, the Company adopted a Nonqualified Deferred Compensation Plan (DCP) to provide non-qualified retirement benefits to a select group of executive officers, senior management and highly compensated employees of the Company. Eligible employees may elect to contribute up to 75% of their annual base salary and 100% of their annual bonus to the DCP and such employee contributions are 100% vested. In addition, the Company may elect to make annual discretionary contributions on behalf of participants in the DCP. Each Company contribution is subject to a three year vesting schedule, such that each contribution vests one third annually. Employee contributions are recorded within accrued expenses in the Consolidated Balance Sheets.

Upon enrollment into the DCP, employees make investment elections for both their voluntary contributions and discretionary contributions, if any, made by the Company. Earnings and losses on contributions based on these investment elections are recorded as a component of compensation expense in the period earned.

Beginning in fiscal 2007, annually the Compensation Committee of the Board of Directors has approved a discretionary cash contribution to the DCP for each year. Discretionary contributions by the Company to the DCP are held in a Rabbi Trust. The Company is recording compensation expense for the DCP discretionary contributions ratably over the three-year vesting period of each annual contribution, and totaled $2.7 million, $2.1 million and $1.8 million in fiscal years 2011, 2010 and 2009, respectively. The full amount of the discretionary contribution, net of forfeitures, is recorded within accrued expenses in the Consolidated Balance Sheets and totaled $17.2 million and $15.9 million at September 24, 2011 and September 25, 2011, respectively.

The Company has purchased Company-owned group life insurance contracts, in which both voluntary and discretionary Company DCP contributions are invested, to fund payment of the Company s obligation to the DCP participants. The total amount invested at September 24, 2011 and September 25, 2010 was $22.7 million and $18.2 million, respectively, which approximated the total of employee voluntary contributions into the plan and the Company s cash portion of its discretionary contribution. The values of these life insurance contracts are recorded with other long-term assets in the Consolidated Balance Sheets. Changes in the cash surrender value of life insurance contracts, which were not significant in fiscal 2011, 2010 and 2009, are recorded as a component of other income (expense), net in the Consolidated Statements of Operations.

12. Commitments and Contingencies

Contingent Earn-Out Payments

In connection with its acquisitions, the Company has incurred the obligation to make contingent earnout payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period. 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 earnout obligations may include covenants to operate the businesses acquired in a manner that may not otherwise be most advantageous to the Company.

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These contingent consideration arrangements are recorded as either additional purchase price or compensation expense if continuing employment is required to receive such payments. Pursuant to ASC 805, contingen