GEN PROBE INC
Form 10-K
February 23, 2012
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 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: 000-49834

Gen-Probe Incorporated

(Exact name of registrant as specified in its charter)

Delaware	**33-0044608**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
10210 Genetic Center Drive, San Diego, CA	**92121-4362**
(Address of principal executive office)	*(Zip Code)*

Registrant s telephone number, including area code:

(858) 410-8000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None

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

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 þ 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ 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 the 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. þ

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 þ	Accelerated filer ¨	Non-accelerated filer ¨	Smaller reporting company ¨
		(Do not check if a 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 þ

As of June 30, 2011, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $3.3 billion, based on the closing price of the registrant s common stock on the NASDAQ Global Select Market on that date. Shares of common stock held by each officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded because these persons may be considered affiliates. The determination of affiliate status for purposes of this calculation is not necessarily a conclusive determination for other purposes.

As of February 16, 2012, 45,229,152 shares of registrant s common stock, $0.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company s definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year are incorporated by reference into Part III of this report.

Table of Contents

GEN-PROBE INCORPORATED

TABLE OF CONTENTS

FORM 10-K

For the Year Ended December 31, 2011

INDEX

Table of Contents

PART I

TRADEMARKS AND TRADE NAMES

ACCUPROBE, AMPLIFIED MTD, APTIMA, APTIMA COMBO 2, DTS, ELUCIGENE, GASDIRECT, GEN-PROBE, GTI DIAGNOSTICS, LEADER, LIFECODES, PACE, PANTHER, PROADENO, PRODESSE, PROFAST, PROFLU, PROGASTRO, PROGENSA, TIGRIS and our other logos and trademarks are the property of Gen-Probe Incorporated or its subsidiaries. PROCLEIX and ULTRIO are trademarks of Novartis Vaccines & Diagnostics, Inc. XMAP is a trademark of Luminex Corporation. AVODART is a trademark of GlaxoSmithKline. All other brand names or trademarks appearing in this Annual Report on Form 10-K, or Annual Report, are the property of their respective holders. Our use or display of other parties trademarks, trade dress or products in this Annual Report does not imply that we have a relationship with, or endorsement or sponsorship of, the trademark or trade dress owners.

FORWARD-LOOKING STATEMENTS

This Annual Report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or if they prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes expressed or implied by the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as believe, expect, hope, may, will, plan, intend estimate, could, should, would, continue, seek or anticipate, or other similar words (including their use in the negative), or by discussio future matters, such as the development and commercialization of new products, technology enhancements, regulatory approvals or clearance, possible changes in legislation and other statements that are not historical. These statements include, but are not limited to, statements under the captions Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as other sections in this Annual Report. You should be aware that the occurrence of any of the events discussed under the heading Item 1A Risk Factors and elsewhere in this Annual Report could substantially harm our business, results of operations and financial condition. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this Annual Report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report.

USE OF EXTERNAL ESTIMATES

This Annual Report includes market share and industry data and forecasts that we obtained from industry publications and surveys. Industry publications, surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of included information. We have not independently verified any of the data from third-party sources nor have we ascertained the underlying economic assumptions relied upon therein. While we are not aware of any misstatements regarding the industry and market data presented herein, the data involve risks and uncertainties and are subject to change based on various factors.

AVAILABLE INFORMATION

We make available free of charge on or through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC. Our Internet address is http://www.gen-probe.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report nor is such information incorporated by reference herein.

Table of Contents

Item 1. ***Business***

Corporate Overview

Gen-Probe Incorporated (NASDAQ: GPRO) is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility. Our molecular diagnostic products are designed to detect diseases more rapidly and/or accurately than older tests, and are among the fastest-growing categories of the *in vitro* diagnostics, or IVD, industry.

We market a broad portfolio of nucleic acid tests, or NATs, to detect infectious microorganisms, including those causing sexually transmitted diseases, or STDs, tuberculosis, strep throat, and other infections. Our leading clinical diagnostics products include our APTIMA family of assays that are used to detect the common STDs chlamydia and gonorrhea, certain high-risk strains of the human papillomavirus, or HPV, and *Trichomonas vaginalis*, the parasite that causes trichomoniasis.

In recent years, we have expanded our portfolio of products through acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel Life Sciences plc, or Tepnel, in April 2009, offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse, Inc., or Prodesse, in October 2009 added a portfolio of real-time polymerase chain reaction, or real-time PCR, products for detecting influenza and other infectious organisms. In addition, in December 2010, we acquired Genetic Testing Institute, Inc., or GTI Diagnostics, a manufacturer of certain of our transplant diagnostic products, as well as specialty coagulation and transfusion-related blood bank products.

In blood screening, we developed and manufacture the PROCLEIX family of assays, which are used to detect human immunodeficiency virus (type 1), or HIV-1, the hepatitis C virus, or HCV, the hepatitis B virus, or HBV, and the West Nile virus, or WNV, in donated human blood. These blood screening products are marketed worldwide by our blood screening collaborator, Novartis Vaccines and Diagnostics, Inc., or Novartis, under Novartis trademarks.

Several of our current and future molecular tests can be performed on our TIGRIS instrument, a fully automated, high-throughput NAT system for diagnostics and blood screening. We are building on the success of our TIGRIS instrument system by commercializing our next-generation PANTHER instrument, which is a versatile, fully automated NAT system for low- to mid-volume laboratories. The PANTHER instrument was CE-marked and launched in Europe for diagnostic use in the fourth quarter of 2010. In addition, in May 2011 we filed a 510(k) application with the United States Food and Drug Administration, or FDA, for clearance of our PANTHER system to run our APTIMA Combo 2 assay for the detection of chlamydia and gonorrhea. In August 2011, Health Canada granted us a medical device license to use the PANTHER system to run our APTIMA Combo 2 assay in Canada. We are also developing the PANTHER system for use in the blood screening market as part of our blood screening collaboration with Novartis.

Our development pipeline includes products to detect:

- certain genotypes of HPV, which can cause cervical cancer;
- gene-based markers for prostate cancer;
- the quantity of certain viruses, often referred to as the viral load ;
- certain gastrointestinal pathogens;
- antigens and antibodies that are used to determine transplant and transfusion compatibility; and
- coagulation disorders.

Table of Contents

Company History

Gen-Probe was founded in 1983, and was incorporated under the laws of the state of Delaware in 1987. In September 2002, we were spun off from Chugai Pharmaceutical Co., Ltd., our former indirect parent, as a separate, stand-alone company. Our common stock began trading on the NASDAQ Global Select Market on September 16, 2002. Our headquarters facility is located in San Diego and we employ approximately 1,400 people.

Recent Events

FDA Clearance of APTIMA Trichomonas Assay

In April 2011, the FDA cleared our APTIMA Trichomonas vaginalis assay for sale and marketing in the United States. The APTIMA Trichomonas assay is an amplified nucleic acid test that detects *Trichomonas vaginalis*, the most common curable sexually transmitted infection in the United States. The APTIMA Trichomonas assay has been approved for use on our fully automated, high-throughput TIGRIS instrument system.

FDA Approval of APTIMA HPV Assay

In October 2011, the FDA approved our APTIMA HPV assay, an amplified nucleic acid test that detects certain high-risk strains of HPV that are associated with cervical cancer and precancerous lesions, for sale and marketing in the United States. The APTIMA HPV assay has been approved for use on our TIGRIS instrument system.

FDA Approval of PROGENSA PCA3 Assay

In February 2012, the FDA approved our PROGENSA PCA3 assay, a prostate cancer specific molecular diagnostic test, for sale and marketing in the United States. The PROGENSA PCA3 assay has been approved for use on our semi-automated Direct Tube Sampling, or DTS, instrument systems.

Stock Repurchase Programs

In February 2011, our Board of Directors authorized the repurchase of up to $150.0 million of our common stock until December 31, 2011, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. We completed the program in August 2011, repurchasing and retiring approximately 2.5 million shares at an average price of $60.00 per share, or approximately $150.0 million in total.

In September 2011, our Board of Directors authorized the repurchase of up to an additional $100.0 million of our common stock from November 2011 through June 2012, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. We completed the program in December 2011, repurchasing and retiring approximately 1.7 million shares at an average price of $58.83 per share, or approximately $100.0 million in total.

Strategy

We intend to increase our scale and expand our geographic reach, both by investing in our existing businesses and by acquiring new businesses that are consistent with our strategy. We intend to compete in the women s health, infectious diseases, blood screening and transplant diagnostics markets, and expand into adjacent markets where our core strengths give us a sustainable competitive advantage. We expect that our PANTHER program will be central to our strategy of bringing superior automation to our customers, and along with TIGRIS, will serve as the core of our instrument platform strategy for the coming years.

Table of Contents

The focus of our women s health strategy will continue to be our chlamydia and gonorrhea business, where we intend to invest in technologies and products to maintain or expand our market share. We are also commercializing our HPV screening assay and related products, with the goal of becoming one of the leaders in this market over time. In addition, we expect to develop and commercialize assays that expand and complement our product menus. For example, we released our APTIMA Trichomonas assay for the detection of *Trichomonas vaginalis* in April 2011.

We have a portfolio of respiratory infectious disease products as a result of our acquisition of Prodesse in October 2009, and we intend to continue to develop products to serve the infectious disease market. We also intend to pursue internal development programs to establish a leadership position in the virology market.

In blood screening, we collaborate with Novartis to ensure the safety of the worldwide blood supply. We intend to continue to work with Novartis to maintain the vitality of our blood screening business by investing in areas that promise strong returns on our investment, and by developing our PANTHER instrument platform in the blood screening market.

Our transplant diagnostics business comprises our human leukocyte antigen, or HLA, products and related assays. We intend to continue to invest in our transplant diagnostics business in order to improve our market positioning, broaden our product offering and further develop our technological capabilities.

We also intend to continue to expand into adjacent markets within clinical diagnostics, beginning with genetic testing, which includes prostate oncology, as well as other markets where we believe we can establish a competitive advantage. We believe that our collaboration with Pacific Biosciences of California, Inc., or Pacific Biosciences, related to genetic sequencing could support our efforts in this area over the longer term. For more information regarding our collaboration with Pacific Biosciences, please see Collaborations and Agreements located elsewhere in the Business section of this Annual Report.

Competitive Strengths

Assay Development

We believe our core technologies and scientific expertise enable us to develop diagnostic and blood screening assays with superior performance over competing NAT products. We measure performance in terms of sensitivity, specificity, speed of results and ease of use. For example, independent investigators have published several studies demonstrating that our APTIMA Combo 2 assay for chlamydia and gonorrhea is more sensitive than competing molecular tests. In addition, we believe we have enhanced our ability to develop infectious disease assays based on real-time PCR technology through our acquisition of Prodesse.

Instrument Development and Automation

We believe we have the capability to develop instrument platforms that offer superior automation. We have commercialized what we believe to be the world s first fully automated, integrated, high-throughput, NAT instrument system, the TIGRIS instrument. Launched in 2004, the TIGRIS instrument significantly reduces labor costs and contamination risks in high-volume diagnostic testing environments, and enables large blood screening centers to individually test donors blood. We are building on the success of TIGRIS by commercializing a new automated instrument platform, called the PANTHER system, designed for low- to mid-volume customers, which we believe will be a pillar in our future instrumentation platform strategy. The PANTHER instrument was CE-marked and launched in Europe in the fourth quarter of 2010 and we filed a 510(k) application with the FDA for clearance of our PANTHER system in the United States to run our APTIMA Combo 2 assay in May 2011. In addition, we have recently initiated development programs to add real-time PCR capabilities for the next-generation PANTHER system and to develop a new, standalone instrument to further automate molecular testing from liquid-based cytology specimens. We believe that the use of automated instrumentation, such as our TIGRIS and PANTHER instruments, will facilitate growth in both the clinical diagnostics and blood screening portions of the NAT market.

Table of Contents

Innovation

As of December 31, 2011, we had 327 full-time and temporary employees in research and development. We believe that compared to our peers, we invest a higher percentage of our revenue in research and development, with expenses totaling $112.7 million in 2011, $111.1 million in 2010 and $106.0 million in 2009. Based on these investments, we had more than 580 United States and foreign patents covering our products and technologies as of December 31, 2011. We were awarded a 2004 National Medal of Technology, the nation s highest honor for technological innovation, in recognition of our pioneering work in developing NAT testing systems to safeguard the blood supply in the United States.

Sales and Service

As of December 31, 2011, our direct sales force consisted of 69 employees and a 68 member technical field support group who target customers in the United States, Canada, Australia and certain countries in Europe. We believe these individuals comprise one of the most knowledgeable and effective sales and support organizations in our industry. Our sales representatives have an average of approximately 13 years of overall sales experience. We view our long-standing relationships with laboratory customers and the value-added services that our sales force and technical field specialist group offer, including technical product assistance, customer support and new product training, as central to our success in the United States clinical diagnostics market, and we are looking to duplicate this success as we expand our sales force in Europe and Australia. We complement our sales force with leading international distributors and the direct sales organizations of our collaborative partners.

Quality

We are committed to quality in our products, operations and people. Our products, design control and manufacturing processes are regulated by numerous third parties, including the FDA, foreign governments, independent standards auditors and customers. Our team of 217 full-time and temporary employees in regulatory, clinical and quality has successfully led us through multiple quality and compliance inspections and audits. For example, our blood screening manufacturing facility meets the strict standards set by the FDA s Center for Biologics Evaluation and Research, or CBER, for the production of blood screening products. We believe our expertise in regulatory and quality assurance and our manufacturing facilities enable us to efficiently and effectively design, manufacture and secure approval for new products and technologies that meet the standards set by governing bodies and our customers. We have implemented modern quality systems and concepts throughout our organization. Our regulatory and quality assurance departments supervise our quality systems and are responsible for assuring compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies, managing regulatory matters and monitoring external quality performance.

Markets

The NAT market developed in response to a need for more rapid, sensitive and specific diagnostic tests for the detection of infectious microorganisms than were previously available using traditional laboratory methods, such as culture and immunoassays. Culture methods require the growth of a microorganism in a controlled medium and can take several days or longer to yield a definitive diagnostic result. By contrast, nucleic acid probes, which specifically bind to nucleic acid sequences that are known to be unique to the target organisms, can generally deliver an accurate diagnostic result in just hours. The greater sensitivity and increased specificity of NATs relative to immunoassays allow for the detection of the presence of a lower concentration of the target organism and help clinicians distinguish between harmful and benign microorganisms, even when the organisms are closely related, reducing the potential for false negative and false positive results. For example, the greater sensitivity of amplified NAT allows for the rapid, direct detection of a target organism like C*hlamydia trachomatis* in urine, even when it is present in low concentrations.

We are focused on NAT market opportunities in women s health, infectious diseases, blood screening and transplant diagnostics. We are also expanding into adjacent areas where we believe our capabilities give us a

Table of Contents

sustainable competitive advantage, beginning with genetic testing, which includes prostate oncology. We believe that our collaboration with Pacific Biosciences related to genetic sequencing could support our efforts in this area over the longer term. In addition, as a result of our acquisition of Tepnel, we also offer services for the pharmaceutical, biotechnology and healthcare industries through our research products and services business, which includes nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

Women s Health

Chlamydia and Gonorrhea. NAT assays are currently used to detect the microorganisms causing various STDs, including chlamydia and gonorrhea, the two most common bacterial STDs. Chlamydia, the common name for the bacterium C*hlamydia trachomatis*, causes the most prevalent bacterial sexually transmitted infection in the United States, with an estimated 2.8 million new cases in the United States each year according to the Centers for Disease Control and Prevention, or CDC. The clinical consequences of undiagnosed and untreated chlamydia infections include pelvic inflammatory disease, ectopic pregnancy and infertility.

Gonorrhea, the disease caused by the bacterium *Neisseria gonorrhoeae*, is the second most frequently reported bacterial STD in the United States, according to the CDC. The CDC estimates that each year approximately 700,000 people in the United States contract gonorrhea. Untreated gonorrhea is also a major cause of pelvic inflammatory disease, which may lead to infertility or abnormal pregnancies. In addition, recent data suggest that gonorrhea facilitates HIV transmission.

Chlamydia and gonorrhea infections frequently co-exist, complicating the clinical differential diagnosis. Because chlamydia and gonorrhea infections are often asymptomatic, screening programs are important in high-risk populations, such as sexually active men and women between the ages of 15 and 25.

According to internal market research, our products represented more than 50% of the total chlamydia and gonorrhea tests sold in the United States in 2011.

Human papillomavirus (HPV). HPV is a group of viruses with more than 100 sub-types, 14 of which have been categorized as high risk for the development of cervical cancer. While most women will be infected with HPV at some point in their lives, the majority of these infections are transient and resolve without any clinical symptoms or consequences. However, a small number of HPV infections progress and result in disease ranging from genital warts to cervical cancer. Since most HPV infections do not result in cancer, there is a need for a more specific test to identify women at greater risk of developing that disease.

The most common test used for cervical cancer screening in the United States is the Pap test. Since the mid-1950s, screening with the Pap test has dramatically reduced the number of deaths from cervical cancer. Even so, the American Cancer Society estimates that there will be more than 12,000 new cases of invasive cervical cancer in 2011, and more than 4,000 deaths from the disease.

Despite the success of Pap testing in reducing mortality from cervical cancer in the United States, it suffers from limitations. One such limitation is poor sensitivity of individual Pap smears, which means the test may miss cancers or precancerous changes. As a result, regular and repeated Pap testing is required to effectively detect a high proportion of cervical cancers. Another limitation is that more than 2 million of the 55 million Pap tests performed annually in the United States have equivocal results, which are known as ASC-US. These women may be subjected to additional invasive tests, including biopsies, most of which prove negative.

In May 2008, we launched our APTIMA HPV assay in Europe. The assay has been CE-marked for use on the TIGRIS system and on our semi-automated DTS instrument systems. The assay is an amplified NAT that is designed to detect 14 sub-types of high-risk HPV that are associated with cervical cancer. More specifically, the assay is designed to detect certain messenger ribonucleic acids, or mRNAs, that are made in greater amounts when HPV infections progress toward cervical cancer. We believe that targeting these mRNAs may more

Table of Contents

accurately identify women at higher risk of having, or developing, cervical cancer than competing assays that target HPV deoxyribonucleic acid, or DNA. In October 2011, the FDA approved our APTIMA HPV assay for sale and marketing in the United States on our fully automated, high-throughput TIGRIS instrument system.

Trichomonas vaginalis. *Trichomonas vaginalis* is a sexually transmitted parasite that can cause vaginitis, urethritis, premature membrane rupture in pregnancy, and make women more susceptible to infection with HIV-1, the virus that causes acquired immune deficiency syndrome, or AIDS. The CDC estimates that there are 7.4 million cases of Trichomonas infection annually in the United States, making it even more prevalent than chlamydia and gonorrhea, the most common bacterial sexually transmitted diseases. Screening for Trichomonas is limited today due in part to the shortfalls of current testing techniques. Most testing currently is done via culture methods, which are slow and less sensitive than molecular tests, or wet mount, which requires the microscopic examination of a sample shortly after it is collected.

In June 2010, our APTIMA *Trichomonas vaginalis* assay was CE-marked for use on the TIGRIS system, which enables the sale of the CE-marked assay in Europe. In April 2011, the FDA cleared our Trichomonas assay for marketing in the United States on the TIGRIS system.

Group B Streptococcus. Group B Streptococcus, or GBS, represents a major infectious cause of illness and death in newborns in the United States and can cause cerebral palsy, visual impairment, permanent brain damage and learning disabilities. Our AccuProbe Group B Streptococcus Culture ID Test offers a rapid, non-subjective method for the identification of GBS based on the detection of specific ribosomal ribonucleic acid, or ribosomal RNA, sequences.

Infectious Diseases

Influenza and Other Respiratory Infections. In October 2009, we added to our existing menu of infectious disease products by acquiring Prodesse, which offers a number of products in the infectious disease market, with current products principally focused on respiratory infections.

Influenza (flu) viruses are a common cause of serious respiratory infections. Flu refers to illnesses caused by a number of different influenza viruses. Flu can cause a range of symptoms from mild to severe, and in some cases the infection can lead to death. Most healthy people recover from the flu without problems, but certain people are at high risk for serious complications. Flu symptoms may include fever, coughing, sore throat, runny or stuffy nose, headaches, body aches, chills and fatigue. In recent years, several strains of flu, including seasonal flu and H1N1pdm09, have circulated in the United States. Like seasonal flu, illness in people with H1N1pdm09 can vary from mild to severe. Annual outbreaks of the seasonal flu usually occur during the late fall through early spring.

We market and sell ProFlu+, a multiplex real-time PCR assay designed to detect and differentiate influenza A and B and respiratory syncytial virus, or RSV, and ProFAST+, a multiplex real-time PCR assay designed to detect and differentiate three sub-types of influenza A: seasonal H1, seasonal H3 and H1N1pdm09, under our Prodesse product line. The ProFAST+ assay was cleared for marketing in the United States by the FDA in July 2010. Our Prodesse product line also includes ProGastro Cd, a real-time PCR assay for the qualitative detection of toxigenic C. difficile, as well as other tests for respiratory infections.

Tuberculosis. Tuberculosis, or TB, the disease caused by the microorganism *Mycobacterium tuberculosis*, remains one of the deadliest diseases in the world. Our amplified Mycobacterium Tuberculosis Direct, or MTD, test has sensitivity similar to a culture test but can detect the TB pathogen within a few hours. In addition, our MTD test is the only approved assay in the United States with a smear negative claim.

Group A Streptococcus. Group A Streptococcus, or GAS, is the cause of strep throat, which if left untreated may cause serious complications, such as rheumatic fever and rheumatic heart disease. Our Group A Streptococcus Direct Test, or GASDirect assay, is a rapid NAT assay for the direct detection of *Streptococcus pyogenes* in one hour from a throat swab.

Table of Contents

Virology. NAT assays can be used to detect viral DNA or RNA in a patient sample. These tests can be qualitative, meaning that the tests simply provide a yes-no answer for the presence or absence of the virus, or quantitative, meaning that the test determines the quantity of virus in the patient sample.

Today, most NAT testing in the virology field is done for HIV and HCV. HIV is the virus responsible for AIDS. Individuals with AIDS show progressive deterioration of their immune systems and become increasingly susceptible to various diseases, including many that rarely pose a threat to healthy individuals. HCV is a blood-borne pathogen posing one of the greatest health threats in developing countries. According to the World Health Organization, or WHO, approximately 80% of newly infected patients progress to develop chronic infection, which can lead to both cirrhosis and liver cancer. The WHO reports that approximately 130 to 170 million people are infected worldwide with HCV. According to the National Cancer Institute, an estimated 4.1 million people in the United States have been infected with HCV, of whom 3.2 million are chronically infected according to the CDC. Most people with chronic HCV infection are asymptomatic.

We have developed and market qualitative NATs for HIV-1 and HCV in the United States. In addition, we sell analyte specific reagents, or ASRs, for quantitative HCV testing in the United States through our collaboration with Siemens Healthcare Diagnostics, Inc., or Siemens. ASRs comprise a category of individual reagents utilized by clinical laboratories to develop and validate their own diagnostic tests. We are currently investigating opportunities to broaden our virology business, and have begun development work on a quantitative HIV assay that would be designed to run on our PANTHER instrument.

Blood Screening

According to the WHO, each year more than 90 million units of blood are donated worldwide. Before being used for transfusion, blood must be screened to ensure that it does not contain infectious agents such as viruses. The most commonly screened viruses are HIV, HCV, WNV and HBV.

Prior to the introduction of NAT for blood screening, blood screening centers primarily used immunoassays to determine the presence of blood-borne pathogens through the detection of virus-specific antibodies and viral antigens. These tests either directly detect the viral antigens or detect antibodies formed by the body in response to the virus. However, this immune response may take some time following initial infection. Consequently, if the donor has not developed detectable antibodies or detectable amounts of viral antigens as of the time of the donation, recipients of that blood may be unwittingly exposed to serious disease. NAT technology can detect minute amounts of virus soon after infection by amplifying the nucleic acid material of the viruses themselves, rather than requiring the development of detectable levels of antibodies or viral antigens.

We believe that our products are used to screen over 80% of the United States donated blood supply for HIV-1, HCV, HBV and WNV.

Transplant Diagnostics

HLA testing, also known as HLA typing or tissue typing, identifies antigens on white blood cells that determine tissue compatibility for organ transplantation (that is, histocompatibility testing). HLA typing, along with blood type grouping, is used to provide evidence of tissue compatibility. The HLA antigens expressed on the surface of the lymphocytes of the recipient are matched against those from various donors. HLA typing is performed for kidney, bone marrow, liver, pancreas, and heart transplants. HLA testing is also performed to reduce the probability of transplant rejection and for the ongoing management of transplant recipients.

Our acquisitions of Tepnel and GTI Diagnostics enabled us to diversify into the transplant typing market. As a result of our Tepnel acquisition, we now sell xMAP multiplex assays in the field of transplant diagnostics under our development and supply agreement with Luminex Corporation, or Luminex. We also offer a range of HLA antibody detection products under our LIFECODES brand, as well as a number of other HLA-related testing products, including serological typing trays, enzyme immunoassays, and a range of molecular typing products for donor-recipient matching and patient monitoring.

Table of Contents

Genetic Testing

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

In November 2006, we launched our CE-marked PROGENSA PCA3 assay, a prostate cancer specific molecular diagnostic test, in Europe. We also offer ASRs for detection of the PCA3 gene in the United States and Canada.

In August 2009, we began a clinical trial intended to secure regulatory approval of our PROGENSA PCA3 assay in the United States. In February 2012, the FDA approved our PROGENSA PCA3 assay for sale and marketing in the United States on our semi-automated DTS instrument systems.

Genetic testing to identify individuals at risk of certain diseases and pathological syndromes is emerging as an additional market for NAT technology. Through our acquisition of Tepnel, we gained access to genetic tests that are CE-marked in Europe for cystic fibrosis, Down Syndrome, and familial hypercholesterolemia, among other diseases.

Key Product Technologies

APTIMA Family of Technologies

Our APTIMA products integrate our patented transcription-mediated amplification, or TMA, technology, target capture technology, and our patented hybridization protection assay, or HPA, and dual kinetic assay, or DKA, technologies, to produce highly refined amplification assays that increase assay performance, improve laboratory efficiency and reduce laboratory costs. Each of these technologies is described in greater detail below.

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

Transcription-Mediated Amplification (TMA) Technology. The goal of amplification technologies is to produce millions of copies of the target nucleic acid sequences that are present in samples in small numbers. These copies can then be detected using DNA probes. Amplification technologies can yield results in only a few hours versus the several days or weeks required for traditional culture methods. Our patented TMA technology is designed to overcome problems faced by other target amplification methods. TMA is a transcription-based amplification system that uses two different enzymes to drive the process. The first enzyme is a reverse transcriptase that creates a double-stranded DNA copy from an RNA or DNA template. The second enzyme, an RNA polymerase, makes thousands of copies of the complementary RNA sequence, known as the RNA amplicon, from the double-stranded DNA template. Each RNA amplicon serves as a new target for the reverse transcriptase and the process repeats automatically, resulting in an exponential amplification of the original target that can produce over a billion copies of amplicon in less than 30 minutes.

Table of Contents

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

Other Product Technologies

Our recent acquisitions have expanded our portfolio to include products in the respiratory disease and HLA fields, among others, which are based on certain third-party technologies, including F. Hoffman-La Roche Ltd. s real-time PCR technology, and Luminex s xMAP technology, each of which is described below.

Real-Time Polymerase Chain Reaction Technology (real-time PCR). Real-time PCR is a laboratory technique based on PCR, which is used to amplify and simultaneously quantify a targeted nucleic acid (DNA or RNA) molecule. Real-time PCR enables both detection and quantification of one or more specific sequences in a nucleic acid sample. Real-time PCR follows the general principle of PCR. Its key feature is that the amplified nucleic acid is detected as the reaction progresses in real time, rather than at the end of the amplification reaction.

Luminex xMAP Technology. Luminex s xMAP technology combines existing biological testing techniques with advanced digital signal processing and proprietary software. With the technology, discrete bioassays are performed on the surface of color-coded microspheres. These microspheres are read in a compact analyzer that utilizes lasers and high-speed digital signal processing to simultaneously identify the bioassay and measure the individual assay results. To perform a bioassay using xMAP technology, a researcher attaches biochemicals, or reagents, to one or more sets of color-coded microspheres, which are then mixed with an extracted test sample. This mixture is injected into an xMAP analyzer, where the microspheres pass single-file in a fluid stream through two laser beams. The first laser excites the internal dyes that are used to identify the color of the microsphere and the test being performed on the surface of the microsphere. The second laser excites a fluorescent dye captured on the surface of the microsphere that is used to quantify the result of the bioassay taking place. Luminex s proprietary optics, digital signal processors and software record the fluorescent signature of each microsphere and compare the results to the known identity of that color-coded microsphere set. The results are analyzed and displayed in real-time with data stored on the computer database for reference, evaluation and analysis.

Key Products

In the tables below we identify some of the key products we offer in the various markets we currently serve. As described in more detail in the Risk Factors section included in Item 1A of this Annual Report, for products that have not received regulatory clearance in one or more jurisdictions, there can be no assurance that such product(s) will be approved for sale in the applicable jurisdiction(s).

Table of Contents

Women s Health

We have established a market-leading position with respect to assays for the detection of chlamydia and gonorrhea, and have obtained several FDA approvals to compete in this market category.

Product Line	Description	Availability
APTIMA Combo 2 assay	Uses APTIMA technology to simultaneously detect chlamydia and gonorrhea.	Marketed globally.
APTIMA CT, APTIMA GC assays	Standalone NATs that use APTIMA technology to detect chlamydia and gonorrhea.	Marketed globally.
APTIMA HPV assay	Uses APTIMA technology to detect 14 sub-types of high-risk HPV associated with cervical cancer.	Marketed globally.
APTIMA Trichomonas assay	Uses APTIMA technology to detect *Trichomonas vaginalis*.	Marketed globally.
APTIMA Trichomonas ASRs	Analyte specific reagents that use APTIMA technology to enable laboratories qualified under the Clinical Laboratory Improvement Amendments, or CLIA, to detect *Trichomonas vaginalis*.	ASRs available in the United States and Canada.
PACE family of assays	Non-amplified NATs to detect chlamydia and gonorrhea.	Marketed globally.
AccuProbe Group B Streptococcus (GBS) assay	Non-amplified NAT to detect GBS from culture.	Marketed globally.

Table of Contents

Infectious Diseases

Our acquisition of Prodesse in October 2009 added assays for certain respiratory and gastrointestinal diseases to our menu of products in this field, which now includes the products described in the table below.

Product Line	Description	Availability
ProFlu+	Uses multiplex real-time PCR to detect and differentiate influenza A, B and Respiratory Syncytial Virus, or RSV.	Marketed globally.
ProFAST+	Uses multiplex real-time PCR to detect and differentiate three influenza A sub-types: seasonal H1, seasonal H3 and H1N1pdm09.	Marketed globally.
ProGastro Cd	Uses real-time PCR to detect toxigenic strains of *Clostridium difficile.*	Marketed globally.
AMPLIFIED MTD	Uses TMA to detect *Mycobacterium tuberculosis.*	Marketed globally.
GAS Direct	Non-amplified NAT to detect GAS directly from a throat swab.	Marketed in the United States and Canada.
APTIMA HIV-1 assay	Uses APTIMA technology to qualitatively detect RNA from HIV-1, the virus that causes AIDS.	Marketed in the United States.
APTIMA HCV assay	Uses APTIMA technology to qualitatively detect RNA from the hepatitis C virus.	Marketed in the United States.
ASRs for quantitative HCV testing	Analyte specific reagents used by laboratories qualified under CLIA to quantify HCV viral load.	Marketed by Siemens in the United States.

Table of Contents

Blood Screening

In 1996, the National Heart, Lung and Blood Institute of the National Institutes of Health, or NIH, selected us to develop reagents and instrumentation for the blood donor screening market based on our core technologies. We completed our development of the NAT assays for HIV-1 and HCV for blood screening contemplated by the NIH contract in February 2002 incorporating our core technologies of TMA, target capture and DKA. The principal blood screening products that we have developed are set forth below.

Product Line	Description	Availability
Procleix HIV-1/HCV assay	Amplified NAT to simultaneously screen for HIV-1 and HCV in donated blood, plasma, organs and tissues.	Marketed globally by Novartis.
Procleix Ultrio assay	Amplified NAT to simultaneously detect HIV-1, HCV and HBV in donated blood, plasma, organs and tissues.	Marketed globally by Novartis.
Procleix Ultrio Plus assay	Amplified NAT to simultaneously detect HIV-1, HCV and HBV in donated blood, plasma, organs and tissues.	Marketed outside the United States by Novartis.
Procleix WNV assay	Amplified NAT to detect West Nile Virus in donated blood, plasma, organs and tissues.	Marketed globally by Novartis.

Transplant Diagnostics

As a result of our acquisitions of Tepnel in April 2009 and GTI Diagnostics in December 2010, we now offer certain products in the transplant diagnostics, specialty coagulation and transfusion-related blood bank markets, including the products described in the table below.

Product Line	Description	Availability
LIFECODES HLA DNA typing kits	Uses the multiplex Luminex xMAP technology and sequence-specific oligonucleotide, or SSO, methodology to determine the HLA type of transplant patients.	Marketed globally.
LIFECODES HLA antibody kits	Uses the multiplex Luminex xMAP platform to screen and identify HLA antibodies present in transplant patients.	Marketed globally.
LIFECODES PF4 assay	An enzyme-linked immunosorbent assay, or ELISA, for the detection of PF4 heparin-dependent antibodies.	Marketed globally.
LIFECODES PAK products	ELISA products designed for platelet antibody screening and detection.	Marketed globally.

Table of Contents

Instrumentation

We have developed and continue to develop instrumentation and software designed specifically for performing our NAT assays. We also provide technical support and instrument service to maintain these systems in the field. By placing our proprietary instrumentation in laboratories and hospitals, we can establish a platform for future sales of our assays. We also sell instruments to Novartis for sale in the blood screening market.

Product Line	Description	Availability
TIGRIS	Integrated, fully-automated testing instrument for high-volume laboratories. Approved to run APTIMA Combo 2, APTIMA CT, APTIMA GC, APTIMA HPV and APTIMA Trichomonas assays, as well as PROCLEIX ULTRIO and PROCLEIX WNV assays.	Marketed globally, including by Novartis in the blood screening market.
DTS (Direct Tube Sampling) instrument systems	Semi-automated instruments that include the DTS 400, 800 and 1600 instruments. Approved to run a number of infectious disease and blood screening assays. In blood screening, also known as the PROCLEIX system, or eSAS.	Marketed globally, including by Novartis in the blood screening market.
PANTHER	Integrated, fully automated testing instrument for low- to mid-volume laboratories.	Marketed in Europe, Canada and Australia; not currently available for sale in the United States or in the blood screening market.

Genetic Testing

In November 2006, we CE-marked our PROGENSA PCA3 assay, allowing it to be marketed in Europe. This gene-based test is designed to detect the over-expression of PCA3 mRNA in urine. Studies have shown that, in greater than 90 percent of prostate cancer cases, PCA3 is highly over-expressed (65-fold on average) in prostate cancer cells compared to normal cells, indicating that PCA3 may be a useful biomarker for prostate cancer. We filed a premarket approval application, or PMA, for our PROGENSA PCA3 assay on the DTS system with the FDA in the third quarter of 2010, which was approved in February 2012.

Product Line	Description	Availability
PROGENSA PCA3	Uses APTIMA technology to quantitatively detect the PCA3 gene, which is over-expressed by cancerous prostate tissue.	Marketed globally.
PCA3 ASRs	Analyte specific reagents used by laboratories qualified under CLIA to detect the PCA3 gene, which is over-expressed by cancerous prostate tissue.	ASRs available in the United States and Canada.

Table of Contents

Customers

The primary customers for our clinical diagnostic products include large reference laboratories, public health institutions and hospitals. Our blood screening products are marketed and distributed worldwide by Novartis under Novartis trademarks. Our blood screening collaboration with Novartis accounted for 36% of our total revenues in 2011 and 37% of our total revenues in 2010. Our blood screening collaboration with Novartis is largely dependent on two significant customers in the United States, The American Red Cross and Creative Testing Solutions, but we do not receive any revenues directly from these entities. Novartis was our only customer that accounted for greater than 10% of our total revenues in 2011.

Marketing Strategy

The focus of our marketing strategy is to solidify awareness of the superiority of our technology, illustrate the cost effectiveness of this technology and continue to differentiate our products from those of our competitors. We target our marketing efforts to various levels of laboratory and hospital management through research publications, print advertisements, conferences and the Internet. We attend various national and regional industry conferences throughout the year. Our web site is used to educate existing and potential customers about our assays and contains our entire directory of products, on-line technical materials and links to related medical sites.

Sales Strategy

We market our products for the clinical diagnostics market to laboratories in the United States, Canada, Australia and certain countries in Europe through our direct sales force. In other countries, we rely on distributors for our clinical diagnostic products. As of December 31, 2011, our direct sales force consisted of a staff of 69 sales employees and a staff of 68 technical field support employees who support our sales efforts. Sales representatives principally focus on large accounts, including reference laboratories, public health institutions and hospitals throughout North America, Australia and certain European countries. Our sales representatives are able to recommend the appropriate business solution to meet the needs of our customers by presenting multiple NAT technology and instrumentation options. Sales representatives are trained to find new product opportunities, offer diagnostic solutions to address unmet customer needs, and provide comprehensive after-sale product support. In addition, our field technical support group provides training and ongoing technical support for all of our NAT products.

Distributors

The blood screening products we manufacture under our collaboration agreement with Novartis are marketed and distributed solely by Novartis under Novartis trademarks. Under our collaboration agreement with Siemens, we and Siemens market our qualitative assays for HCV and Siemens distributes ASRs for the quantitative detection of the amount of HCV present in a sample.

We also rely on a network of independent distributors with experience and expertise in clinical diagnostic products for the distribution of certain of our products in various territories throughout the world. Distribution rights revert back to us upon termination of the applicable distribution agreement.

Collaborations and Agreements

Co-Exclusive License from Stanford University

In August 1988, we obtained a license from Stanford University granting us rights under specified patent applications covering certain nucleic acid amplification methods related to TMA. This license was amended in April 1997. Under the amended license agreement, we are the co-exclusive worldwide licensee of the Stanford amplification technology, with Organon Teknika as the only other permitted Stanford licensee. We paid a license fee and are obligated to make royalty payments to Stanford based on net sales of products incorporating the licensed technology, subject to a minimum annual royalty payment. From inception through December 31, 2011,

Table of Contents

we incurred a total of $21.6 million in expenses under this agreement, including $3.5 million in expenses during 2011. Our obligation to make royalty payments under this agreement terminates when the patents constituting the Stanford amplification technology expire, which is expected to occur in July 2017. This agreement may be terminated by Stanford upon a material breach of the agreement by us that is not cured following 60 days written notice.

Women s Health

Supply and Purchase Agreement with Roche. In February 2005, we entered into a supply and purchase agreement with F. Hoffman-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc., which we refer to collectively as Roche. Under this agreement, Roche agreed to manufacture and supply us with oligonucleotides for HPV, which we use in our molecular diagnostic assays. Pursuant to the agreement, we paid Roche manufacturing access fees of $20.0 million in May 2005 and $10.0 million in May 2008, upon the first commercial sale of our CE-marked APTIMA HPV assay in Europe. We also agreed to pay Roche transfer fees for the HPV oligonucleotides we purchase. The agreement terminates upon the expiration of Roche s patent rights relevant to the agreement and may be terminated earlier in certain other limited circumstances.

In December 2006, Digene Corporation, or Digene, filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution, or ICDR, of the American Arbitration Association that asserted, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and sought a determination that the supply and purchase agreement was null and void. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. In April 2009, following the arbitration hearing, a three-member arbitration panel from the ICDR issued an interim award rejecting all claims asserted by Digene (now Qiagen Gaithersburg, Inc.). In August 2009, the arbitrators issued their final arbitration award, which confirmed the interim award and also granted our motion to recover attorneys fees and costs from Digene in the amount of approximately $2.9 million. We filed a petition to confirm the arbitration award in the United States District Court for the Southern District of New York and Digene filed a petition to vacate or modify the award. In August 2010, the court confirmed the arbitration award and we received the $2.9 million from Digene, which was recorded as an offset to general and administrative expense.

Infectious Diseases

Agreement with Siemens Healthcare Diagnostics, Inc. (formerly Bayer Corporation). We supply our TMA assay for the qualitative detection of HCV to Siemens pursuant to a collaboration agreement. We also supply Siemens with ASRs for the quantitative detection of HCV. Under the terms of the agreement, Siemens pays us a combination of transfer prices and royalties on sales of the HCV assays and reagents. We recognized $1.2 million in revenue during 2011 under our collaboration agreement with Siemens.

Blood Screening

Agreement with Novartis (formerly Chiron Corporation). The development, manufacture, marketing and sale of our blood screening products is governed by the terms of our collaboration agreement with Novartis, which was originally executed in 1998 and subsequently amended on numerous occasions. In July 2009, we entered into an amended and restated collaboration agreement with Novartis, which sets forth the current terms of the parties blood screening collaboration. The term of the collaboration agreement runs through June 30, 2025, unless terminated earlier pursuant to its terms under certain specified conditions. Under the collaboration agreement, we manufacture blood screening products, while Novartis is responsible for marketing, sales and service of those products, which Novartis sells under its trademarks.

Starting in 2009, we were entitled to recover 50% of our manufacturing costs incurred in connection with the collaboration and will receive a percentage of the blood screening assay revenue generated under the

Table of Contents

collaboration. Our share of revenue from any assay that includes a test for HCV is as follows: 2009, 44%; 2010-2011, 46%; 2012-2013, 47%; 2014, 48%; and 2015 through the remainder of the term of the collaboration, 50%. Our share of blood screening assay revenue from any assay that does not test for HCV remains at 50%. Novartis has also reduced the amount of time between product sales and payment of our share of blood screening assay revenue from 45 days to 30 days.

Novartis has also agreed to provide certain funding to customize our PANTHER instrument for use in the blood screening market and to pay us a milestone payment upon the earlier of certain regulatory approvals or the first commercial sale of the PANTHER instrument for use in the blood screening field. The parties will share equally in any profit attributable to Novartis sale or lease of PANTHER instruments under the collaboration.

From inception through December 31, 2011, we recognized a total of $1.7 billion in revenue under our collaboration with Novartis and have recorded $2.1 million in deferred license revenues as of December 31, 2011.

Genetic Testing

Exclusive License with DiagnoCure. In November 2003, we entered into a license, development and cooperation agreement with DiagnoCure under which we agreed to develop in collaboration with DiagnoCure, and we agreed to market, a test to detect a new gene marker for prostate cancer. The diagnostic test is directed at the PCA3 gene that has been shown by studies to be over expressed in malignant prostate tissue. Under the terms of the agreement, we paid DiagnoCure an upfront fee as well as certain additional fees and contract development payments. We received exclusive worldwide distribution rights under the agreement to any products developed by the parties under the agreement for the diagnosis of prostate cancer, and agreed to pay DiagnoCure royalties on any such products of 8% on cumulative net product sales of up to $50.0 million, and royalties of 16% on cumulative net sales above $50.0 million. We began paying royalties under this agreement in 2006. Unless terminated earlier pursuant to specified terms, the agreement expires, on a country-by-country basis, on the expiration of our obligation to pay royalties to DiagnoCure, which obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed patent rights.

In April 2009, we amended our license, development and cooperation agreement with DiagnoCure. Pursuant to this amendment, our exclusive license in the United States with respect to the licensed PCA3 marker could be converted into a co-exclusive license (with DiagnoCure) in the United States under certain conditions, including our failure to timely file an application with the FDA for regulatory approval of a PCA3 assay in the United States. In addition, we agreed to use commercially reasonable efforts to obtain FDA approval of specified PCA3 assays and to file an application with the FDA for regulatory approval of a PCA3 assay in the United States by a specified date. We also agreed to make annual payments of $0.5 million to DiagnoCure until specific milestones are met. We may apply half of the annual payments against future royalties due and payable to DiagnoCure under the license, development and cooperation agreement. We filed a PMA for our PROGENSA PCA3 assay on the DTS system with the FDA in the third quarter of 2010, which was approved in February 2012.

We also paid $5.0 million to purchase 4.9 million shares of DiagnoCure preferred stock, which is convertible at our election into DiagnoCure common stock on a one-to-one basis. The preferred stock has a liquidation preference over DiagnoCure s common stock, which is secured by certain intellectual property collateral. DiagnoCure has the right to convert the preferred stock into common stock under certain circumstances and may redeem the preferred stock at any time prior to conversion at a specified price.

License Agreement with University of Michigan. In April 2006, we entered into a license agreement with the University of Michigan, or the University, for exclusive worldwide rights to develop and commercialize diagnostic tests for recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue. We agreed to pay the University an up-front fee and royalties on eventual product sales, as well as development milestones. In addition, we agreed to fund certain research at the

Table of Contents

University to discover other potential prostate cancer translocations. The agreement will terminate upon the expiration or abandonment of the last to expire of the licensed patent rights. The University has the right to terminate the agreement upon written notice to us if we materially breach the agreement. We may terminate the agreement upon 45 days written notice to the University, provided we have paid all amounts owed to the University and delivered reports and other data due and owing under the agreement.

Collaboration with and Investment in Pacific Biosciences. In June 2010, we entered into a collaboration agreement with Pacific Biosciences regarding the research and development of instruments integrating our sample preparation technologies and Pacific Biosciences single-molecule DNA sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the initial term of the collaboration will end on the earlier of December 15, 2012 or six months after Pacific Biosciences demonstrates the proof of concept of its V2 single-molecule DNA sequencing system.

Concurrently with the execution of the collaboration agreement, we also purchased $50.0 million of Pacific Biosciences Series F preferred stock as a participant in Pacific Biosciences Series F preferred stock financing, which raised a total of approximately $109.0 million. In October 2010, Pacific Biosciences completed an initial public offering of its common stock, and the stock now trades on the NASDAQ Global Select Market under the symbol PACB. As a result of the initial public offering, our preferred stock was converted into common stock. During the third quarter of 2011, we recorded an other-than-temporary impairment, or OTTI, loss of $39.5 million related to our investment in Pacific Biosciences, which reduced our cost basis in the Pacific Biosciences common stock from $50.0 million to $10.5 million. As of December 31, 2011, our investment in Pacific Biosciences had a value of $9.2 million. For more information regarding this OTTI loss, please see the discussion under the heading Other-than-temporary Impairment Loss on Equity Investment in the Management s Discussion and Analysis of Financial Condition and Results of Operations section located elsewhere in this Annual Report.

Instrumentation

Agreements with Stratec. In November 2006, we entered into a development agreement and a supply agreement with Stratec Biomedical Systems AG, or Stratec, relating to our PANTHER instrument system. Although the development of the original PANTHER instrument system has been completed, we continue to work with Stratec on various enhancements to add new features and functionality to the instrument, including projects relating to development of the PANTHER for the blood screening market and to add real-time PCR functionality. Both parties have the right to terminate the development agreement for insolvency of the other party or for a material breach that is not cured within 80 days of written notice. The supply agreement has an initial term of ten years. Both parties have the right to terminate the supply agreement for insolvency of the other party or for a material breach that is not cured within 80 days of written notice.

Spin-off of Industrial Testing Assets to Roka Bioscience, Inc.

In September 2009, we spun-off our industrial testing assets to Roka Bioscience, Inc., or Roka, a newly formed private company. In consideration for our contribution of assets to Roka in connection with the transaction, we received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis. As part of the spin-off transaction, our industrial testing collaboration agreements with GE Water (a division of GE Energy, a business unit of General Electric) and Millipore Corporation were transferred to Roka. In May 2011, we entered into a supply agreement with Roka, pursuant to which Roka has the right to purchase PANTHER instruments from us for use in certain industrial markets. As of December 31, 2011, we owned approximately 14.7% of Roka calculated on a fully-diluted basis.

Patents and Proprietary Rights

To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade secret laws, as well as confidentiality provisions in our contracts.

Table of Contents

We have implemented a patent strategy designed to maximize our intellectual property rights. We have obtained and are currently pursuing patent coverage in the United States and those foreign countries that are home to the majority of our anticipated customer base. As of December 31, 2011, we owned more than 580 issued United States and foreign patents. In addition, our patent portfolio includes pending patent applications in the United States and corresponding international filings in certain foreign countries. The last of our currently issued patents will expire by February 16, 2030. In addition, from time to time we may seek to enter into license agreements with third parties, pursuant to which we may license certain of our technologies to third parties in exchange for royalties or other payments as specified in the applicable license agreement. Our continued success will depend to a significant degree upon our ability to develop proprietary products and technologies and to obtain patent coverage for those products and technologies. We intend to continue to file patent applications covering novel and newly developed products and technologies.

We also rely in part on trade secret protection for our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. The source code for our proprietary software is protected both as a trade secret and as copyrighted work. Our employees also sign agreements requiring that they assign to us their interests in inventions and original expressions and any corresponding patents and copyrights arising from their work for us. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, there may not be an adequate corrective remedy available to us.

Competition

The medical diagnostics and biotechnology industries are subject to intense competition. Our competitors in the United States and abroad are numerous and include, among others, Roche, Abbott Laboratories, through its subsidiary Abbott Molecular Inc., which we refer to collectively as Abbott, Becton, Dickinson and Company, or BD, Siemens, QIAGEN N.V., or Qiagen, One Lambda, Inc., or One Lambda, and bioMérieux S.A., or bioMérieux. All of these companies are manufacturers of laboratory-based tests and instruments for the NAT market, and we believe that many of these companies are developing automated systems similar to our TIGRIS and PANTHER instruments. In addition, numerous other companies have announced their intention to enter the market.

Many of our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than we do. Moreover, many of our competitors offer broader product lines and have greater brand recognition than we do, and offer price discounts as a competitive tactic. In addition, our competitors, many of which have made substantial investments in competing technologies, may limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

Competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue or market acceptance. Some of our competitors have developed real-time or kinetic nucleic acid assays and semi-automated instrument systems for those assays. Additionally, some of our competitors are developing assays that permit the quantitative detection of multiple analytes, or quantitative multiplexing. Although we are evaluating and/or developing such technologies, we believe some of our competitors are further along in the development process than we are.

In the markets for clinical diagnostic products, a number of competitors, including Roche, Abbott, BD, Siemens, Qiagen, bioMérieux and Hologic, Inc., or Hologic, compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings.

Table of Contents

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

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

Government Regulation

Our clinical diagnostic products generally are classified in the United States as devices and are regulated by the FDA s Center for Devices and Radiological Health, or CDRH. Our blood screening products generally are classified in the United States as biologics and are regulated by CBER.

For us to market our clinical diagnostic products as medical devices in the United States, we generally must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FFDCA, or, if those products are not considered to be substantially equivalent to a legally marketed device, approval of a PMA, which requires human clinical trials. Clinical trials must be conducted in accordance with Good Clinical Practice under protocols generally submitted to the FDA.

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

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. In addition to potential product specific post-approval requirements, all devices are subject to:

- the Quality System Regulation, which requires manufacturers to follow comprehensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations;
- the FDA s general prohibition against promoting products for unapproved or off-label uses; and
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur.

Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA s refusal to grant future premarket approvals or clearances, withdrawals or suspensions of current product applications, suspension of export certificates and criminal prosecution.

20

Table of Contents

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

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

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote biologics, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has broad enforcement authority under the FFDCA, and failure to abide by applicable FDA regulations can result in penalties, including the issuance of a warning letter requiring corrective advertising, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We and our contract medical product manufacturers are subject to periodic inspection by the FDA and other authorities where applicable, and are required to comply with the applicable FDA current Good Manufacturing Practice regulations. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation, and provide for manufacturing facilities to be inspected by the FDA. Manufacturers of biologics also must comply with the FDA s general biological product regulations. These regulations often include lot release testing by the FDA.

Certain assay reagents may be sold as ASRs without 510(k) clearance or PMA approval. However, ASR products are subject to significant restrictions. The manufacturer may not make clinical or analytical performance claims for the product, may not promote their use with additional laboratory equipment and may only sell the product to clinical laboratories that are qualified to run high complexity tests under CLIA. Each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory developed test. We currently offer several ASR products including ASRs for use in the detection of the PCA3 gene and for use in the detection of the parasite *Trichomonas vaginalis.* In September 2007, the FDA published guidance for ASRs that define the types of products that can be sold as ASRs. Under the terms of this guidance and the ASR Manufacturer Letter issued in June 2008 by the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA, it may be more challenging for us to market some of our ASR products and we may be required to terminate those ASR product sales, conduct clinical studies and make submissions of our products to the FDA for clearance or approval.

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

We are also subject to various state and local laws and regulations in the United States relating to laboratory practices and the protection of the environment. In each of these areas, as above, regulatory agencies have broad regulatory and enforcement powers, including the ability to levy fines and civil and criminal penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Table of Contents

Manufacturing and Raw Materials

We own two manufacturing facilities in the United States. Our Genetic Center Drive manufacturing facility in San Diego, California is dedicated to producing our clinical diagnostic products. In 1999, we completed our Rancho Bernardo manufacturing facility in San Diego, California for the manufacture of our blood screening products. This facility meets the strict standards set by CBER for the production of blood screening products. In the U.S we also lease facilities with manufacturing operations in Stamford, Connecticut and Waukesha, Wisconsin.

Outside of the United States, we have manufacturing facilities in Cardiff in the United Kingdom, as well as in Besancon, France. In addition, we are in the process of consolidating our United Kingdom manufacturing operations in our recently expanded facility in Manchester, which we expect to complete in early 2012. We believe that our existing manufacturing facilities provide us with capacity to meet the needs of our currently anticipated growth.

We rely on one contract manufacturer for the production of each of our instrument product lines. For example, KMC Systems, Inc., or KMC Systems, is the only manufacturer of our TIGRIS instrument and Stratec is the only manufacturer of our PANTHER instrument. We have no firm long-term commitments from KMC Systems, Stratec or any of our other contract manufacturers to supply instruments to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order.

We use a diverse and broad range of raw materials in the design, development and manufacture of our products. Although we produce some of our materials on site at our manufacturing facilities, we purchase most of the materials and components used to manufacture our products from external suppliers. In addition, we purchase many key raw materials from single source suppliers. For example, our current supplier of key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is the Roche Molecular Biochemicals division of Roche Diagnostics GmbH, an affiliate of Roche Molecular Diagnostics, which is one of our primary competitors. Although we generally consider and identify alternative suppliers, we do not typically pursue alternative sources due to the strength of our existing supplier relationships.

Employees

As of December 31, 2011, we had 1,391 full-time employees, of whom 304 hold advanced degrees, and 136 temporary employees. Of those full-time and temporary employees, 474 were in operations, 327 were in research and development, 280 were in sales and marketing, 229 were in general and administrative, and 217 were in regulatory, clinical and quality systems. None of our employees is covered by a collective bargaining agreement, and we believe we have a good relationship with our employees.

Geographic Information

For geographic information regarding our revenues, see Note 16 to the Consolidated Financial Statements included elsewhere in this Annual Report.

Item 1A. ***Risk Factors***

Our quarterly revenue and operating results may vary significantly in future periods and our stock price may decline.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenues are unpredictable and may fluctuate due to changes in demand for our products, including fluctuations in demand or inventory levels for blood screening tests and instrumentation from our blood screening collaboration partner Novartis, the timing of acquisitions, the execution of customer contracts, the receipt of milestone payments, or the failure to achieve and receive the same, and the initiation or termination of corporate

Table of Contents

collaboration agreements. In addition, a significant portion of our costs can also vary substantially between quarterly or annual reporting periods. For example, the total amount of research and development costs in a period often depends on the amount of costs we incur in connection with manufacturing developmental lots and clinical trial lots. Moreover, a variety of factors may affect our ability to make accurate forecasts regarding our operating results. For example, certain of our products have a relatively limited sales history, which limits our ability to accurately project future sales, prices and related sales cycles. In addition, we base our internal projections of blood screening product sales and international sales of various diagnostic products on projections prepared by our distributors of these products and therefore we are dependent upon the accuracy of those projections. We expect continuing fluctuations in our manufacture and shipment of blood screening products and instruments to Novartis, which vary each period based on Novartis inventory levels and supply chain needs. In addition, our respiratory infectious disease product line is subject to significant seasonal fluctuations. Furthermore, failure to achieve our operational goals may inhibit our targeted growth plans and the successful implementation of our strategic objectives. Because of all of these factors, our operating results in one or more future quarters may fail to meet or exceed financial guidance we may provide from time to time and the expectations of securities analysts or investors, which could cause our stock price to decline. In addition, the trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about our business and that of our competitors.

Our financial performance may be adversely affected by current global economic conditions.

Our business depends on the overall demand for our products and on the economic health of our current and prospective customers. Our projected revenues and operating results are based on assumptions concerning certain levels of customer demand. Although these effects are difficult to quantify, we believe that relative to our expectations we have experienced modest declines in product sales growth rates in recent periods, due in part to current macroeconomic conditions and pressures on health care utilization. A continued weakening of the domestic or global economies or a reduction in customer spending or credit availability, including as a result of actual or potential debt default by certain European countries, could result in decreased health care utilization, downward pricing pressures, the reduction or elimination of third-party payor coverage and/or reimbursement levels for our products, longer sales cycles and delayed or decreased purchases of our products. Furthermore, during challenging economic times our customers may face issues gaining timely access to sufficient credit, which could result in an impairment of their ability to make timely payments to us. If that were to occur, we may be required to increase our allowance for doubtful accounts. If economic and market conditions in the United States, Europe or other key markets persist, spread, or deteriorate further, we may experience adverse effects on our business, operating results and financial condition.

We are dependent on Novartis and other third parties for the distribution of some of our products. If any of our distributors terminates its relationship with us or fails to adequately perform, our product sales will suffer.

We rely on Novartis to distribute blood screening products we manufacture. Commercial product sales to Novartis accounted for 36% and 39% of our total product sales for 2011 and 2010, respectively. In January 2009, we extended the term of our blood screening collaboration with Novartis to June 30, 2025, subject to earlier termination under certain limited circumstances specified in the collaboration agreement. In addition, we supply our TMA assay for the qualitative detection of HCV and ASRs for the quantitative detection of HCV to Siemens pursuant to a collaboration agreement. We also rely on distributors for the distribution of certain of our products in various territories throughout the world. Distribution rights revert back to us upon termination of the distribution agreements.

If any of our distribution or marketing agreements is terminated, particularly our collaboration agreement with Novartis, or if we elect to distribute new products directly, we will have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. We may not be able to enter into new distribution or marketing agreements

Table of Contents

on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to successfully market our products, our product sales will decrease. We may also be exposed to risks as a result of transitioning a territory from a distributor sales model to a direct sales model, such as difficulties maintaining relationships with specific customers or hiring appropriately trained personnel, any of which could result in lower revenues than we previously received from our distributor in that territory.

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

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

In June 2010, for example, we entered into a collaboration agreement with Pacific Biosciences regarding the research and development of instruments integrating our sample preparation technologies and Pacific Biosciences single-molecule DNA sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the initial term of the collaboration will end on the earlier of December 15, 2012 or six months after Pacific Biosciences demonstrates the proof of concept of its V2 single-molecule DNA sequencing system.

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

If any of our current collaboration agreements is terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to devote additional internal resources to product development or marketing or to terminate some development programs or seek alternative corporate collaborations. We may not be able to negotiate additional corporate collaborations on acceptable terms, if at all, and these collaborations may not be successful. In addition, in the event of a dispute under our current or any future collaboration agreements, such as our agreements with Novartis, Siemens and Pacific Biosciences, a court or arbitrator may not rule in our favor and our rights or obligations under an agreement subject to a dispute may be adversely affected, which may have an adverse effect on our business or operating results.

We may acquire other businesses or form collaborations, strategic alliances and joint ventures that could decrease our profitability, result in dilution to stockholders or cause us to incur debt or significant expense, and acquired companies or technologies could be difficult to integrate and could disrupt our business.

As part of our business strategy, we intend to pursue acquisitions of complementary businesses and enter into technology licensing arrangements. We may also pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. Any future acquisitions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company may also require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all.

In April 2009 we acquired Tepnel, which we believe has provided us with access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, and accelerated our ongoing strategic efforts

Table of Contents

to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe. In October 2009 we acquired Prodesse, which we believe has supported our strategic focus on commercializing differentiated molecular tests for infectious diseases. In addition, in December 2010 we acquired GTI Diagnostics, which we believe has strengthened our transplant diagnostics business and provided us access to the specialty coagulation and transfusion-related blood bank markets. Our beliefs regarding the merits of these acquisitions are based upon numerous assumptions that are subject to risks and uncertainties that could deviate materially from our expectations and could adversely affect our operating results.

Managing the acquisitions of Tepnel, Prodesse and GTI Diagnostics, as well as any other future acquisitions, will entail numerous operational and financial risks, including:

- the anticipated financial performance and estimated cost savings and other synergies as a result of the acquisitions may not materialize;
- the inability to retain or replace key employees of any acquired businesses or hire enough qualified personnel to staff any new or expanded operations;
- the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;
- the exposure to federal, state, local and foreign tax liabilities in connection with any acquisition or the integration of any acquired businesses;
- the exposure to unknown liabilities;
- higher than expected acquisition and integration costs that could cause our quarterly and annual operating results to fluctuate;
- increased amortization expenses if an acquisition includes significant intangible assets;
- combining the operations and personnel of acquired businesses with our own, which could be difficult and costly;
- the risk of entering new markets; and
- integrating, or completing the development and application of, any acquired technologies and personnel with diverse business and cultural backgrounds, which could disrupt our business and divert our management s time and attention.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would result in dilution to our stockholders. If the price of our equity is low or volatile, we may not be able to use our common stock as consideration to acquire other companies. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our future success will depend in part upon our ability to enhance existing products and to develop, introduce and commercialize new products.

The markets for our products are characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products. We believe that we will need to continue to provide new products that can detect and quantify a greater number of organisms from a single sample. We also believe that we must develop new assays that can be performed on automated instrument platforms. The development of new instrument platforms, if any, in turn may require the modification of existing assays for use with the new instrument, and additional time-consuming and costly regulatory approvals. For example, our failure to successfully develop and commercialize our PANTHER instrument system, or our failure to modify existing assays or develop new assays for use with the PANTHER instrument system, on a timely basis could have a negative impact on our financial performance.

Table of Contents

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological, market and medical practice trends, as well as precise technological execution. In addition, the successful development of new products will depend on the development of new technologies. We may be required to undertake time-consuming and costly development activities and to seek regulatory approval for these new products. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of these new products. We have experienced delays in receiving FDA clearance in the past. Regulatory clearance or approval of any new products or instruments we may develop, such as our PANTHER instrument system, may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and these and other new products may not be successfully commercialized. Failure to timely achieve regulatory approval for our products and introduce products to market could negatively affect our growth objectives and financial performance.

We face intense competition, and our failure to compete effectively could decrease our revenues and harm our profitability and results of operations.

The clinical diagnostics industry is highly competitive. Currently, the majority of diagnostic tests used by physicians and other health care providers are performed by large reference, public health and hospital laboratories. We expect that these laboratories will compete vigorously to maintain their dominance in the diagnostic testing market. In order to achieve market acceptance of our products, we will be required to demonstrate that our products provide accurate, cost-effective and time saving alternatives to tests performed by traditional laboratory procedures and products made by our competitors.

In the markets for clinical diagnostic products, a number of competitors, including Roche, Abbott, BD, Siemens, QIAGEN, One Lambda, bioMérieux and Hologic, currently compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. Our existing competitors or new market entrants may be in a better position than we are to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners. Many of our competitors have, and in the future these and other competitors may have, significantly greater financial, marketing, sales, manufacturing, distribution and technological resources than we do. Moreover, these companies may have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do, any of which may adversely affect our customer retention and market share.

Competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue or market acceptance. Some of our competitors have developed real-time or kinetic nucleic acid assays and semi-automated instrument systems for those assays. Additionally, some of our competitors are developing assays that permit the quantitative detection of multiple analytes (or quantitative multiplexing). Although we are evaluating and/or developing such technologies, we believe some of our competitors are further along in the development process than we are with respect to such assays and instrumentation.

In the market for blood screening products, the primary competitor to our collaboration with Novartis is Roche, which received FDA approval of its PCR-based NAT tests for blood screening in December 2002 and received FDA approval of a multiplex real-time PCR assay to screen donated blood in December 2008. Our collaboration with Novartis also competes with blood banks and laboratories that have internally developed assays based on PCR technology, Ortho-Clinical Diagnostics, Inc., a subsidiary of Johnson & Johnson that markets an HCV antigen assay, and Abbott and Siemens with respect to immunoassay products. In the future, our collaboration blood screening products may also compete with viral inactivation or reduction technologies and blood substitutes.

Table of Contents

We believe the global blood screening market is maturing rapidly. We believe the competitive position of our blood screening collaboration with Novartis in the United States remains strong. However, outside of the United States, blood screening testing volume is generally more decentralized than in the United States, customer contracts typically turn over more rapidly and the number of new countries yet to adopt nucleic acid testing for blood screening is diminishing. As a result, we believe geographic expansion opportunities for our blood screening collaboration with Novartis may be narrowing and that we will face increasing price competition within the nucleic acid blood screening market.

Novartis also retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening using NAT. Prior to its merger with Novartis, Chiron granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron also granted HIV and HCV licenses in the clinical diagnostics field to Bayer Healthcare LLC (now Siemens), together with the right to grant certain additional HIV and HCV sublicenses in the field to third parties. We believe Bayer s rights have now been assigned to Siemens as part of Bayer s December 2006 sale of its diagnostics business. Chiron also granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux) in the clinical diagnostics field. If Novartis grants additional licenses in blood screening or Siemens grants additional licenses in clinical diagnostics, further competition will be created for sales of HCV and HIV assays and these licenses could affect the prices that can be charged for our products.

Failure to manufacture our products in accordance with product specifications could result in increased costs, lost revenues, customer dissatisfaction or voluntary product recalls, any of which could harm our profitability and commercial reputation.

Properly manufacturing our complex nucleic acid products requires precise technological execution and strict compliance with regulatory requirements. We may experience problems in the manufacturing process for a number of reasons, such as equipment malfunction or failure to follow specific protocols. If problems arise during the production of a particular product lot, that product lot may need to be discarded or destroyed. This could, among other things, result in increased costs, lost revenues and customer dissatisfaction. If problems are not discovered before the product lot is released to the market, we may incur recall and product liability costs. In the past, we have voluntarily recalled certain product lots for failure to meet product specifications. Any failure to manufacture our products in accordance with product specifications could have a material adverse effect on our revenues, profitability and commercial reputation.

Disruptions in the supply of raw materials and consumable goods or issues associated with their quality from our single source suppliers, including Roche Molecular Biochemicals, which is an affiliate of one of our primary competitors, could result in a significant disruption in sales and profitability.

We purchase some key raw materials and consumable goods used in the manufacture of our products from single-source suppliers. If we cannot obtain sufficient raw materials from our key suppliers, production of our own products may be delayed or disrupted. In addition, we may not be able to obtain supplies from replacement suppliers on a timely or cost-effective basis, or at all. A reduction or stoppage in supply while we seek a replacement supplier would limit our ability to manufacture our products, which could result in a significant reduction in sales and profitability.

In addition, an impurity or variation from specification in any raw material we receive could significantly delay our ability to manufacture products. Our inventories may not be adequate to meet our production needs during any prolonged supply interruption. We also have single source suppliers for proposed future products. Failure to maintain existing supply relationships or to obtain suppliers for our future products on commercially reasonable terms would prevent us from manufacturing our products and limit our growth.

Our current supplier of certain key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is Roche Molecular Biochemicals. We have a supply and purchase agreement for oligonucleotides for HPV with Roche Molecular Systems. Each of these entities is an affiliate of Roche Diagnostics GmbH, one of our primary competitors.

Table of Contents

We have only one third-party manufacturer for each of our instrument product lines, which exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is the only manufacturer of our TIGRIS instrument; MGM Instruments, Inc., or MGM Instruments, is the only manufacturer of our LEADER series of luminometers; and Stratec is the only manufacturer of our PANTHER instrument. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.

We have no firm long-term commitments from KMC Systems to supply products to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order. If KMC Systems, MGM Instruments, Stratec or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its development or manufacturing operations or becomes insolvent or otherwise fails to supply us with products in sufficient quantities, then instrument shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation. Further, because we place orders with our manufacturers based on forecasts of expected demand for our instruments, if we inaccurately forecast demand we may be unable to obtain adequate manufacturing capacity or adequate quantities of components to meet our customers delivery requirements, or we may accumulate excess inventories.

We may in the future need to find new contract manufacturers to replace existing suppliers, increase our volumes or reduce our costs. We may not be able to find contract manufacturers that meet our needs, and even if we do, qualifying a new contract manufacturer and commencing volume production is expensive and time consuming. For example, we believe qualifying a new manufacturer of our TIGRIS instrument would take approximately 12 months and require regulatory approvals. If we are required or elect to change contract manufacturers, we may lose revenues and our customer relationships may suffer.

Our products are subject to various governmental regulations, which may result in us incurring significant compliance costs or experiencing delays or difficulties in commercializing our products.

The clinical diagnostic and blood screening products we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. We generally are prohibited from marketing our clinical diagnostic products in the United States unless we obtain either 510(k) clearance or premarket approval from the FDA. In August 2010, the FDA s CDRH issued two reports outlining potential changes to the 510(k) regulatory process. In addition, in January 2011, the CDRH issued an implementation plan containing 25 specific actions to be implemented in 2011 relating to the 510(k) regulatory process and associated administrative matters. The CDRH also deferred action on several other initiatives, including the creation of a new class of devices that would be subject to heightened review processes, until the IOM released a related report on the 510(k) regulatory process in July 2011. The FDA is reviewing the IOM s report as well as public input to determine what, if any, recommendations the FDA will adopt with respect to the 510(k) regulatory process. Many of the actions proposed by the CDRH could result in significant changes to the 510(k) regulatory process, which would likely complicate the process of getting products cleared by the FDA. Delays in receipt of, or failure to obtain, clearances or approvals for future products could delay or preclude realization of product revenues from new products or result in substantial additional costs which could decrease our profitability.

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

Table of Contents

The process of seeking and obtaining regulatory approvals to market our products, particularly from the FDA and some foreign governmental authorities, can be costly and time consuming, and approvals might not be granted for future products on a timely basis, or at all. In addition, unexpected complications in conducting clinical trials could cause us to incur unanticipated expenses or result in delays or difficulties in receiving FDA approval or clearance. In May 2011, we submitted an application to the FDA for clearance to use our PANTHER instrument system to run our APTIMA Combo 2 assay. There can be no assurances as to whether the use of our PANTHER instrument system will be approved for sale in the United States on a timeline consistent with our expectations, or at all. Failure to obtain or delay in obtaining FDA clearance or approval of our PANTHER instrument system or any of our newly developed assays could have a material adverse effect on our financial performance.

We are also required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product. These requirements include, among other things, the Quality System Regulation, labeling requirements, the FDA s general prohibition against promoting products for unapproved or off-label uses and adverse event reporting regulations. Failure to comply with applicable FDA product regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications and criminal prosecution. Any of these actions, in combination or alone, could prevent us from selling our products and harm our business.

Certain assay reagents may be sold in the United States as ASRs without 510(k) clearance or premarket approval from the FDA. However, the FDA restricts the sale of these ASR products to clinical laboratories certified to perform high complexity testing under CLIA, and also restricts the types of products that can be sold as ASRs. In addition, each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory developed test. We currently offer several ASR products including ASRs for use in the detection of PCA3 RNA and for use in the detection of *Trichomonas vaginalis* RNA. We also have developed an ASR for the detection of HCV RNA that Siemens provides to Quest Diagnostics Incorporated. In September 2007, the FDA published guidance that defines the types of products that can be sold as ASRs. Under the terms of this guidance and the ASR Manufacturer Letter issued in June 2008 by the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA, it may be more challenging for us to market some of our ASR products and we may be required to terminate those ASR product sales, conduct clinical studies and make submissions of our ASR products to the FDA for clearance or approval.

In addition to ASRs, certain research use only, or RUO, products may be sold in the United States without 510(k) clearance or premarket approval from the FDA. The FDA generally considers RUO products as products that are in the laboratory research phase of development and which are not represented as an effective *in vitro* diagnostic product. We currently sell certain RUO products for immunology and DNA extraction purposes. In June 2011, the FDA issued draft guidance indicating that RUO product manufacturers should not sell RUO products to customers whom they know use the product for clinical diagnostic use. Comments to the FDA s draft guidance were due in August 2011. If the FDA issues final guidance imposing obligations on RUO product manufacturers as proposed in the draft guidance, we will be subject to additional restrictions, which may include potentially having to cease sales of RUO products to certain customers, and we will likely incur increased compliance costs related to the sale of our RUO products.

The use of our diagnostic products is also affected by CLIA and related federal and state regulations governing laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some clinical laboratories from using some or all of our diagnostic products.

Table of Contents

As both the FDA and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Complying with these rules and regulations could cause us to incur significant additional expenses and delays in launching products, which would harm our operating results.

Our products are subject to recalls even after receiving FDA approval or clearance.

The FDA and governmental bodies in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to product manufacturing, quality, labeling, advertising, or promotional activities, or if new information is obtained concerning the safety of a product. Our assay products incorporate complex biochemical reagents and our instruments comprise complex hardware and software. We have in the past voluntarily recalled products, which, in each case, required us to identify a problem and correct it. In December 2008, we recalled certain AccuProbe test kits after receiving a customer complaint indicating the customer had received a kit containing a probe reagent tube that appeared upon visual inspection to be empty. We confirmed that a manufacturing error had occurred, corrected the problem, recalled all potentially affected products, provided replacements and notified the FDA and other appropriate authorities. In March 2011, we received a letter from the FDA classifying our December 2008 voluntary recall as a Class 1 recall, the most serious of the recall classifications used by the FDA. In May 2011, we voluntarily recalled certain Elucigene test kits for the detection of genetic mutations associated with cystic fibrosis because of issues we identified during quality control stability testing. All affected customers and appropriate regulatory authorities have been advised of the voluntary recall and we have made a substitute product available. The affected product is CE marked, but is not cleared by the FDA and is not available for sale in the United States. In addition, in May 2011 we initiated a second voluntary recall of certain Elucigene branded tests in Canada upon determination that such products were not properly registered with Health Canada.

Although none of our past product recalls had a material adverse effect on our business, our products may be subject to a future government-mandated recall or further voluntary recalls, and any such recalls could divert managerial and financial resources, could be more difficult and costly to correct, could result in the suspension of sales of certain of our products and could harm our reputation and our financial results.

Our gross profit margin percentage on the sale of blood screening assays may decrease upon the implementation of smaller pool size or individual donor testing.

We currently receive revenues from the sale of blood screening assays primarily for use with pooled donor samples, particularly in the United States. In pooled testing, multiple donor samples are initially screened by a single test. Since Novartis sells blood screening assays under our collaboration to blood screening centers primarily on a per donation basis, our profit margins are greater when a single test can be used to screen multiple donor samples.

Many international blood screening markets have transitioned from pooled testing of large numbers of donor samples to smaller pool sizes or individual donor testing, or IDT. A greater number of tests are required in markets which have adopted smaller pool sizes or IDT. Under our collaboration agreement with Novartis, we bear half of the cost of manufacturing blood screening assays. The greater number of tests required for smaller pool sizes or IDT will increase our variable manufacturing costs, including costs of raw materials and labor. If the price per donor or total sales volume does not increase in line with the increase in our total variable manufacturing costs, our gross profit margin percentage from sales of blood screening assays will decrease upon adoption of smaller pool sizes or IDT. We are not able to predict accurately the ultimate extent to which our gross profit margin percentage will be negatively affected as a result of smaller pool sizes or IDT, because we do not know the ultimate selling price that Novartis may charge to the end user or the degree to which smaller pool size or IDT will be adopted across the markets in which our products are sold.

Table of Contents

Because we depend on a small number of customers for a significant portion of our product sales, the loss of any of these customers or any cancellation or delay of a large purchase by any of these customers could significantly reduce our revenues.

Historically, a limited number of customers have accounted for a significant portion of our product sales, and we do not have any long-term commitments with these customers, other than pursuant to our collaboration agreement with Novartis. Product sales from our blood screening collaboration with Novartis accounted for 35% and 39% of our total product sales for 2011 and 2010, respectively. Our blood screening collaboration with Novartis is largely dependent on two significant customers in the United States, The American Red Cross and Creative Testing Solutions, although we do not receive any revenues directly from those entities. Novartis was our only customer that accounted for greater than 10% of our total revenues during 2011 and 2010. We anticipate that our operating results will continue to depend to a significant extent upon revenues from a small number of customers. The loss of any of our key customers, or a significant reduction in sales volume or pricing to those customers, could significantly reduce our revenues.

Intellectual property rights on which we rely to protect the technologies underlying our products may be inadequate to prevent third parties from using our technologies or developing competing products.

Our success will depend in part on our ability to obtain patent protection for, or maintain the secrecy of, our proprietary products, processes and other technologies for the development of blood screening and clinical diagnostic products and instruments. Although we had more than 580 U.S. and foreign patents covering our products and technologies as of December 31, 2011, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by February 16, 2030 and the patents we may obtain in the future also will expire over time.

The scope of any of our issued patents may not be broad enough to offer meaningful protection. In addition, others may challenge our current patents or patents we may obtain in the future and, as a result, these patents could be narrowed, invalidated or rendered unenforceable, or we may be forced to stop using the technology covered by these patents or to license technology from third parties.

In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011 the United States enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the United States from a first-to-invent system to a first to file system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the United States. Any patents issued to us or our collaborators may not provide us with any competitive advantages, and the patents held by other parties may limit our freedom to conduct our business or use our technologies. Our efforts to enforce and maintain our intellectual property rights may not be successful and may result in substantial costs and diversion of management time. Even if our rights are valid, enforceable and broad in scope, third parties may develop competing products based on technology that is not covered by our patents.

In addition to patent protection, we also rely on copyright and trademark protection, trade secrets, know-how, continued technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of our trade secrets and proprietary information, we require our employees, consultants, advisors and others to whom we disclose confidential information to execute confidentiality and proprietary information

Table of Contents

and inventions agreements. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, adequate corrective remedies may not be available. Furthermore, like many companies in our industry, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information and inventions agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market and execute our business strategies.

The diagnostic products industry has a history of patent and other intellectual property litigation, and we have been and may continue to be involved in costly intellectual property lawsuits.

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. From time-to-time in the ordinary course of business, we receive communications from third parties calling our attention to patents or other intellectual property rights owned by them, with the implicit or explicit suggestion that we may need to acquire a license of such rights. We have faced in the past, and may face in the future, patent infringement lawsuits by companies that control patents for products and services similar to ours or other lawsuits alleging infringement by us of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may choose to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management s attention from other business concerns. The cost of such litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

In October 2009, we filed a patent infringement action against BD in the United States District Court for the Southern District of California. The complaint alleges that BD s Viper XTR testing system infringes five of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint also alleges that BD s ProbeTec Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA assays used with the Viper XTR testing system infringe two of our U.S. patents covering penetrable caps for specimen collection tubes. The complaint seeks monetary damages and injunctive relief. In March 2010, we filed a second complaint for patent infringement against BD in the U.S. District Court for the Southern District of California alleging that BD s BD MAX System (formerly known as the HandyLab Jaguar system) infringes four of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The second complaint also seeks monetary damages and injunctive relief. In June 2010, these two actions were consolidated into a single legal proceeding. There can be no assurances as to the final outcome of this litigation.

Pursuant to our collaboration agreement with Novartis, we hold certain rights in the blood screening and clinical diagnostics fields under patents originally issued to Novartis covering the detection of HIV. We sell a qualitative HIV test in the clinical diagnostics field and we manufacture tests for HIV for use in the blood screening field, which Novartis sells under Novartis brands and name. In February 2005, the U.S. Patent and Trademark Office declared two interferences related to U.S. Patent No. 6,531,276 (Methods For Detecting Human Immunodeficiency Virus Nucleic Acid), originally issued to Novartis. The first interference was between Novartis and the NIH, and pertained to U.S. Patent Application No. 06/693,866 (Cloning and Expression of HTLV-III DNA). The second interference was between Novartis and Institut Pasteur, and pertained to Institut Pasteur s U.S. Patent Application No. 07/999,410 (Cloned DNA Sequences, Hybridizable with Genomic RNA of Lymphadenopathy-Associated Virus (LAV)). We were informed that the Patent and

Table of Contents

Trademark Office determined that Institut Pasteur invented the subject matter at issue prior to NIH and Novartis. We were also informed that Novartis and NIH subsequently filed actions in the U.S. District Court for the District of Columbia challenging the decisions of the Patent and Trademark Office in the patent interference cases. From November 2007 through September 2008, the parties engaged in settlement negotiations and then notified the court that they had signed a memorandum of understanding prior to the negotiation of final, definitive settlement documents. In May 2008, we signed a license agreement with Institut Pasteur concerning Institut Pasteur s intellectual property for the molecular detection of HIV, covering products manufactured and sold through, and under, our brands or name. In September 2008, the parties to the pending litigation in the U.S. District Court for the District of Columbia informed the court that they were unable to reach a final, definitive agreement and intended to proceed with litigation. There can be no assurances as to the ultimate outcome of the interference litigation and no assurances as to how the outcome of the interference litigation may affect the patent rights we licensed from Institut Pasteur, or Novartis right to sell HIV blood screening tests.

The United States health care reform law could adversely affect our business, profitability and stock price.

Comprehensive health care reform legislation has been signed into law in the United States. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of our assays and instruments. This tax is scheduled to take effect in 2013. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through price increases, spending cuts or other actions are unsuccessful, the increased tax burden would adversely affect our financial performance, which in turn could cause the price of our stock to decline.

Our indebtedness could adversely affect our financial health.

In February 2009, we entered into a credit agreement with Bank of America which provided for a one-year senior secured revolving credit facility in an amount of up to $180.0 million that is subject to a borrowing base formula. Subject to the terms of the credit agreement, including the amount of funds that we are permitted to borrow from time to time under the credit agreement, the revolving credit facility has a sub-limit for the issuance of letters of credit in a face amount of up to $10.0 million. In March 2009, we and Bank of America amended the credit facility to increase the amount which we may borrow from time to time under the credit agreement from $180.0 million to $250.0 million. The term of our credit facility with Bank of America has been extended three times and currently expires in February 2013. As of December 31, 2011, the total principal amount outstanding under the revolving credit facility was $248.0 million.

Our indebtedness could have important consequences. For example, it could:

- increase our vulnerability to general adverse economic and industry conditions;
- have a material adverse effect on our business and financial condition if we are unable to service our indebtedness or refinance such indebtedness;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- place us at a disadvantage compared to our competitors that have less indebtedness; and
- expose us to higher interest expense in the event of increases in interest rates because indebtedness under our credit facility bears interest at a variable rate.

In addition, we must comply with certain affirmative and negative covenants under the credit agreement, including covenants that limit or restrict our ability to, among other things, merge or consolidate, change our

33

Table of Contents

business, and permit the borrowings to exceed a specified borrowing base, subject to certain exceptions as set forth in the credit agreement. If we default under the senior secured credit facility, because of a covenant breach or otherwise, the outstanding amounts thereunder could become immediately due and payable.

We may be subject to future product liability claims that may exceed the scope and amount of our insurance coverage, which would expose us to liability for uninsured claims.

While there is a federal preemption defense against product liability claims for medical products that receive premarket approval from the FDA, such defense may not be available for products that we market under a 510(k) clearance. As such, we are subject to potential product liability claims as a result of the design, development, manufacture and marketing of certain of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could cause an increase in our product liability insurance rates. In addition, our insurance policies have various exclusions, and thus we may be subject to a product liability claim for which we have limited or no insurance coverage, in which case we may have to pay the entire amount of any award. In addition, insurance varies in cost and can be difficult to obtain, and we may not be able to obtain insurance in the future on terms acceptable to us, or at all. A successful product liability claim brought against us in excess of our insurance coverage, or which our insurance policies do not cover, may require us to pay substantial amounts, which could harm our business and results of operations.

We are exposed to risks associated with acquisitions and other long-lived and intangible assets that may become impaired and result in an impairment charge.

As of December 31, 2011, we had approximately $513.6 million of long-lived assets, including $17.0 million of capitalized software, net of accumulated amortization, relating primarily to our TIGRIS and PANTHER instruments, goodwill of $140.4 million, a $5.4 million investment in Qualigen, Inc., a $5.0 million investment in DiagnoCure, a $4.7 million investment in Roka, and $165.0 million of capitalized licenses and manufacturing access fees, patents, purchased intangible assets and other long-term assets. Additionally, we had $67.5 million of land and buildings, $33.0 million of building improvements, $72.8 million of equipment and furniture and fixtures and $2.8 million in construction in progress. The substantial majority of our long-lived assets are located in the United States.

The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. These events or changes might include a significant decline in market share, a significant decline in profits, rapid changes in technology, significant litigation, an inability to successfully deliver an instrument to the marketplace and attain customer acceptance or other matters. Adverse events or changes in circumstances may affect the estimated undiscounted future operating cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. In the past we have incurred, and in the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

Future changes in financial accounting standards or practices, or existing taxation rules or practices, may cause adverse unexpected revenue or expense fluctuations and affect our reported results of operations.

A change in accounting standards or practices, or a change in existing taxation rules or practices, can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or standards, such as the potential requirement that United States registrants prepare financial statements in accordance with International Financial Reporting Standards, or the questioning of current practices may

Table of Contents

adversely affect our reported financial results or the way we conduct our business. Our effective tax rate can also be impacted by changes in estimates of prior years items, past and future levels of research and development, or R&D, spending, the outcome of audits by federal, state and foreign jurisdictions, the availability of the federal R&D tax credit and, in some instances, the timing of when this tax credit is made available to us, and changes in overall levels of income before tax.

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

Historically, we have incurred significant costs in connection with the development of blood screening and clinical diagnostic products, as well as our TIGRIS and PANTHER instrument systems. We expect that our R&D expense levels will remain high as we seek to expand our product offerings and continue to develop products and technologies in collaboration with our partners. As a result, we will need to continue to generate significant revenues to maintain current levels of profitability. Although we expect that our R&D expenses as a percentage of revenue will decrease in future periods, we may not be able to generate sufficient revenues to maintain current levels of profitability in the future. A potential reduction of profitability in the future could cause the market price of our common stock to decline.

Our marketable securities are subject to market and investment risks which may result in a loss of value.

We engage one or more third parties to manage some of our cash consistent with an investment policy that restricts investments to debt securities of high credit quality, with requirements placed on maturities and concentration by security type and issue. These investments are intended to preserve principal while providing liquidity adequate to meet our projected cash requirements. Risk of principal loss is intended to be minimized through diversified short and medium term investments of high quality, but these investments are not, in every case, guaranteed or fully insured. In light of recent changes in the credit market, some high quality short term investment securities, similar to the types of securities that we invest in, have suffered illiquidity, events of default or deterioration in credit quality. If our short term investment portfolio becomes affected by any of the foregoing or other adverse events, we may incur losses relating to these investments. In addition, the Pacific Biosciences common stock we hold, which trades on the NASDAQ Global Select Market under the symbol PACB, is also subject to various market and investment risks. In the third quarter of 2011, we recognized a $39.5 million OTTI loss related to our investment in Pacific Biosciences. We may be exposed to additional losses in the value of our investment in Pacific Biosciences as a result of a further decline in the trading price of Pacific Biosciences common stock.

We may not have financing for future capital requirements, which may prevent us from addressing gaps in our product offerings or improving our technology.

Although historically our cash flow from operations has been sufficient to satisfy working capital and capital expenditure and R&D requirements, we may in the future need to incur debt or issue equity in order to fund these requirements, as well as to make acquisitions and other investments. If we cannot obtain debt or equity financing on acceptable terms or are limited with respect to incurring debt or issuing equity, we may be unable to address gaps in our product offerings or improve our technology, particularly through acquisitions or investments.

If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation and may contain other provisions that adversely affect the rights of the holders of our common stock. The terms of any debt securities may impose restrictions on our operations. If we raise funds through the issuance of equity or debt convertible into equity, such financing would result in dilution to our stockholders.

Table of Contents

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

Our products must be manufactured in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs and complying with regulatory requirements. In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products we and our distributors require, which could harm our business and results of operations.

Significant additional work will be required for scaling-up manufacturing of each new product prior to commercialization, and we may not successfully complete this work. Manufacturing and quality control problems have arisen and may arise in the future as we attempt to scale-up our manufacturing of a new product, and we may not achieve scale-up in a timely manner, at a commercially reasonable cost or at all. In addition, although we expect some of our newer products and products under development to share production attributes with certain of our existing products, production of these newer products may require the development of new manufacturing technologies and expertise, which we may be unable to develop.

The amplified NAT tests that we produce are significantly more expensive to manufacture than our non-amplified products. As we continue to develop new amplified NAT tests in response to market demands for greater sensitivity, our product costs will increase significantly and our margins may decline. We sell our products in a number of cost-sensitive market categories, and we may not be able to manufacture these more complex amplified tests at costs that would allow us to maintain our historical gross margin percentages. In addition, new products that detect or quantify more than one target organism will contain significantly more complex reagents, which will increase the cost of our manufacturing processes and quality control testing. We or other parties we engage to help us may not be able to manufacture these products at a cost or in quantities that would make these products commercially viable. If we are unable to develop or contract for manufacturing capabilities on acceptable terms for our products under development, we will not be able to conduct pre-clinical, clinical and validation testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates.

Blood screening and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States and the EU, certain products may also require individual lot release testing. Maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other regulatory agencies, and these facilities are subject to FDA requirements relating to the Quality System Regulation. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 28% and 27% of our total revenues for 2011 and 2010, respectively. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 51% and 58% of our total international revenues for 2011 and 2010, respectively.

We encounter risks inherent in international operations. We expect a significant portion of our sales growth to come from expansion in international markets. In addition, our international sales have increased as a result of our acquisition of Tepnel and other international expansion efforts. If the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. Our international sales also may be limited or disrupted by:

the imposition of government controls;

Table of Contents

export license requirements;

economic and political instability;

price controls;

trade restrictions and tariffs;

differing local product preferences and product requirements; and

changes in foreign medical reimbursement and coverage policies and programs.

If third-party payors do not reimburse our customers for the use of our clinical diagnostic products or if they reduce reimbursement levels, our ability to sell our products will be harmed.

We sell our clinical diagnostic products primarily to large reference laboratories, public health institutions and hospitals, substantially all of which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other government programs, private insurance plans and managed care programs. Most of these third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors may also refuse to reimburse for experimental procedures and devices. In addition, foreign medical reimbursement rules are not always consistent with the rules in the United States and often differ from country to country, which complicates the process of introducing new products in foreign jurisdictions.

Third-party payors reimbursement policies may affect sales of our products that screen for more than one pathogen at the same time, such as our APTIMA Combo 2 product for screening for the causative agents of chlamydia infections and gonorrhea in the same sample. Third-party payors may choose to reimburse our customers on a per test basis, rather than on the basis of the number of results provided by the test. This may result in our customers electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, these entities likely would purchase separate tests for each disease, rather than products that test for more than one microorganism.

In addition, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and price levels of our products. If our customers are not reimbursed for our products, they may reduce or discontinue purchases of our products, which would cause our revenues to decline.

We are dependent on technologies we license, and if we fail to maintain our licenses or license new technologies and rights to particular nucleic acid sequences for targeted diseases in the future, we may be limited in our ability to develop new products.

We are dependent on licenses from third parties for some of our key technologies. For example, our patented TMA technology is based on technology we have licensed from Stanford University. In addition, we have acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure. We enter into new licensing arrangements in the ordinary course of business to expand our product portfolio and access new technologies to enhance our products and develop new products. Many of these licenses provide us with exclusive rights to the subject technology or disease marker. If our license with respect to any of these technologies or markers is terminated for any reason, we may not be able to sell products that incorporate the technology. In addition, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license.

Our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such

Table of Contents

discoveries are made. Our ability to design products that target these diseases may depend on our ability to obtain the necessary rights from the third parties that make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT assays may be economically viable. If we are unable to access new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

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

If we fail to attract, hire and retain qualified personnel, we may not be able to design, develop, market or sell our products or successfully manage our business.

Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of any one of our management personnel or our inability to identify, attract, retain and integrate additional qualified management personnel could make it difficult for us to manage our business successfully, attract new customers, retain existing customers and pursue our strategic objectives. Although we have employment agreements with our executive officers, we may be unable to retain our existing management. We do not maintain key person life insurance for any of our executive officers.

Competition for skilled sales, marketing, research, product development, engineering, and technical personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of the services of key personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop new products or enhance existing products in a timely manner, sell products to our customers or manage our business effectively.

If a natural or man-made disaster strikes our manufacturing or warehouse facilities, we may be unable to manufacture or distribute our products for a substantial amount of time and may experience inventory shortfalls, which would cause our sales to decline.

We manufacture substantially all of our products in four manufacturing facilities, two of which are located in San Diego, California, one of which is located in Waukesha, Wisconsin and the other is located in Stamford, Connecticut. These facilities and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. In addition, we use a third-party logistics provider to store product inventory in the United States. Our facilities or those of our third-party logistics provider may be harmed by natural or man-made disasters or events, including, without limitation, earthquakes, tornadoes, fires and prolonged power outages. In the event any of these facilities is affected by such a disaster or event, we would be forced to rely on third-party manufacturers and may experience inventory shortages. In the event of a disaster or other similar event, we may lose customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

In addition, we may also suffer disruptions in our ability to ship products to customers or otherwise operate our business as a result of other natural disasters, such as the eruptions of a volcano in Iceland which necessitated the closing of a significant portion of the airspace over Europe for several days and caused the cancellation of thousands of airline flights during April 2010 or the earthquake and tsunami in Japan during March 2011. The occurrence of other natural disasters having a similar effect could harm our business and results of operations.

Table of Contents

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.

Our R&D activities and our manufacturing activities involve the controlled use of infectious agents and potentially harmful biological materials, as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury, and we could be held liable for damages that result from any contamination or injury. In addition, we are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The damages resulting from any accidental contamination and the cost of compliance with environmental laws and regulations could be significant.

The anti-takeover provisions of our certificate of incorporation and bylaws, and provisions of Delaware law, could delay or prevent a change of control that our stockholders may favor.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or other change of control that our stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management. Among other things, the provisions of our amended and restated certificate of incorporation and amended and restated bylaws:

divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms;

limit the right of stockholders to remove directors;

regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders; and

authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

In addition, because we have not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that our stockholders may favor. Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisition of additional shares, for a three-year period following the date on which that person or its affiliate crosses the 15% stock ownership threshold.

If we do not effectively manage our growth, it could affect our ability to pursue opportunities and expand our business.

Growth in our business, including as a result of acquisitions, has placed and will likely continue to place a significant strain on our personnel, facilities, management systems and resources. We need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce in order to effectively manage our growth. In addition, we will have to maintain close coordination among our various departments and locations. If we fail to effectively manage our growth, it could adversely affect our ability to pursue business opportunities and expand our business.

Information technology systems implementation issues or security threats could disrupt our internal operations and adversely affect our financial results.

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have implemented an enterprise resource planning software system to replace our various legacy systems. To more fully realize the potential of this system, we are continually reassessing and upgrading processes and this may be

Table of Contents

more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the operation of this system or any future systems or any unauthorized access to our information systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows and to otherwise operate our business in a secure environment, all of which could adversely affect our financial results, stock price and reputation.

Compliance with changing corporate governance and public disclosure regulations may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and Nasdaq Global Select Market rules, are creating uncertainty for companies such as ours. To maintain high standards of corporate governance and public disclosure, we have invested, and intend to continue to invest, in reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

Our worldwide headquarters are located in our two adjacent facilities located on Genetic Center Drive in San Diego, California. We own each of the facilities and the underlying land. The first facility is 262,000 square feet. The second facility consists of a 291,000 square foot shell, with approximately 221,000 square feet built-out. The remaining expansion space can be used to accommodate future growth. We own an additional facility in San Diego, California, consisting of 94,000 square feet, where we manufacture our blood screening products.

We are consolidating our Waukesha, Wisconsin operations into a single 60,000 square foot facility, which we occupy pursuant to a long-term lease that expires in June 2025. This facility supports our infectious disease and transplant diagnostics businesses. We also lease a 37,000 square foot facility in Stamford, Connecticut, which supports our transplant diagnostics business. The Stamford lease currently runs through April 2015.

In the United Kingdom, we own a 23,000 square foot facility in Cardiff, Wales and a 19,000 square foot facility in Livingston, Scotland, as well as lease space in Manchester, England. During the second quarter of 2010, we initiated a plan to consolidate our operations in the United Kingdom to Manchester and Livingston in order to accommodate the anticipated growth in the business and to optimize expenses. In connection with this consolidation we entered into a new lease covering our facility in Manchester, which increased the size of the leased space to approximately 57,000 square feet. The lease for the Manchester facility is a 25 year lease which runs through August 2035. We also lease a second 9,000 square foot facility in Manchester, England, which operates primarily as a warehouse and distribution center. The lease for the warehouse operations currently runs through October 2015.

Additionally, we lease space in the following locations: Aachen, Germany; Abingdon, England; Antwerp, Belgium; Besancon, France; Tokyo, Japan; and Wiesbaden, Germany.

Item 3. ***Legal Proceedings***

We are a party to the following litigation and may also be involved in other litigation arising in the ordinary course of business from time to time. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

Table of Contents

Becton, Dickinson and Company

In October 2009, we filed a patent infringement action against BD in the United States District Court for the Southern District of California. The complaint alleges that BD s Viper XTR testing system infringes five of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint also alleges that BD s ProbeTec Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA assays used with the Viper XTR testing system infringe two of our U.S. patents covering penetrable caps for specimen collection tubes. The complaint seeks monetary damages and injunctive relief. In March 2010, we filed a second complaint for patent infringement against BD in the United States District Court for the Southern District of California alleging that BD s BD MAX System (formerly known as the HandyLab Jaguar system) infringes four of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The second complaint also seeks monetary damages and injunctive relief. In June 2010, these two actions were consolidated into a single legal proceeding. There can be no assurances as to the final outcome of this litigation.

Enzo Life Sciences, Inc.

In January 2012, we were sued by Enzo Life Sciences, Inc., or Enzo, in the United States District Court for the District of Delaware. Enzo alleges that we have infringed United States patent number 6,992,180 through the manufacture and sale of molecular diagnostic assays that incorporate our patented HPA technology. The products alleged to infringe include our APTIMA Combo 2 assay and APTIMA HPV assay. We intend to vigorously defend the lawsuit. There can be no assurances as to the final outcome of this litigation.

Item 4. ***Mine Safety Disclosures***

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock has been traded on the NASDAQ Global Select Market since September 16, 2002 under the symbol GPRO. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sale prices for our common stock as reported on the NASDAQ Global Select Market for the periods indicated:

2011	High	Low
First Quarter	$ 66.60	$ 57.91
Second Quarter	$ 86.96	$ 64.65
Third Quarter	$ 69.99	$ 53.92
Fourth Quarter	$ 64.22	$ 54.24

2010	High	Low
First Quarter	$ 50.21	$ 42.19
Second Quarter	$ 51.33	$ 42.60
Third Quarter	$ 49.52	$ 42.00
Fourth Quarter	$ 59.75	$ 46.95

As of February 16, 2012, there were 5,881 stockholders of record of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

Issuer Purchases of Equity Securities

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
October 1-31, 2011		$		$ 100,000,000
November 1-30, 2011	549,300	59.31	549,300	67,421,956
December 1-31, 2011	1,150,652	58.60	1,150,569	
Total [(1)(2)]	1,699,952		1,699,869	

(1) In September 2011, our Board of Directors authorized the repurchase of up to $100.0 million of our common stock from November 2011 through June 2012, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. We completed the stock repurchase program in December 2011, repurchasing and retiring approximately 1.7 million shares at an average price of $58.83 per share, or approximately $100.0 million in total.

(2) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced plans or programs is due to the shares of common stock withheld by us for the payment of taxes upon vesting of certain employees restricted stock. During the fourth quarter of 2011, we repurchased and retired 83 shares of our common stock, at an average price of $62.05, withheld by us to satisfy employee tax obligations upon vesting of restricted stock granted under our 2003 Incentive Award Plan. We may make similar repurchases in the future to satisfy employee tax obligations upon vesting of restricted stock.

Table of Contents

Item 6. ***Selected Financial Data***

SELECTED FINANCIAL INFORMATION

The selected financial data set forth below with respect to our consolidated statements of income for each of the three years in the period ended December 31, 2011 and with respect to our consolidated balance sheets, at December 31, 2011 and 2010 are derived from our consolidated financial statements that have been audited by Ernst & Young LLP, independent registered public accounting firm, which are included elsewhere in this Annual Report. The statement of income data for the years ended December 31, 2008 and 2007 and the balance sheet data as of December 31, 2009, 2008 and 2007 are derived from our audited consolidated financial statements that are not included in this Annual Report. The selected financial information set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this Annual Report.

	2011	2010	2009	2008	2007
	(In thousands, except per share data)				
Statement of income data for the years ended December 31:					
Revenues:					
Product sales	$ 562,588	$ 522,709	$ 483,759	$ 429,220	$ 370,877
Collaborative research revenue	7,682	14,518	7,911	20,581	16,619
Royalty and license revenue	5,964	6,100	6,632	22,894	15,518
Total revenues	576,234	543,327	498,302	472,695	403,014
Total operating expenses	449,984	405,482	378,188	327,300	303,720
Income from operations	126,250	137,845	120,114	145,395	99,294
Net income[1]	$ 50,124	$ 106,937	$ 91,783	$ 106,954	$ 86,140
Net income per share[1]:					
Basic	$ 1.06	$ 2.20	$ 1.82	$ 1.98	$ 1.62
Diluted	$ 1.04	$ 2.18	$ 1.79	$ 1.95	$ 1.58
Weighted average shares outstanding[2]:					
Basic	47,254	48,560	50,356	53,740	52,860
Diluted	48,387	49,033	50,965	54,785	54,355
Balance sheet data as of December 31:					
Cash, cash equivalents and current marketable securities[3]	$ 305,810	$ 230,338	$ 485,606	$ 431,398	$ 395,417
Working capital[3]	164,883	93,259	333,560	506,457	480,321
Total assets	1,045,448	1,167,797	1,128,185	869,531	789,053
Long-term obligations	7,831	6,654	16,215	2,162	1,893
Stockholders equity[1] [4]	700,342	823,379	767,175	813,760	738,040

(1) In 2011, we recorded an OTTI loss on an equity investment and goodwill and asset impairment charges of $39.5 million and $12.7 million, respectively.

(2) Effective January 1, 2009, we adopted guidance issued by the Financial Accounting Standards Board which addresses whether instruments granted in share-based payment transactions are participating securities and therefore have a potentially dilutive effect on earnings per share. This guidance was applied retroactively to all periods presented. The impact on previously reported earnings per share was not material.

(3) In 2009, we began reporting investments that are in an unrealized loss position deemed to be temporary with a contractual maturity of greater than 12 months as non-current marketable securities. Our working capital at December 31, 2010 decreased $240.3 million from December 31, 2009. This decline in working capital resulted from a $243.8 million increase in our non-current marketable securities from December 31, 2009 to

43

Table of Contents

December 31, 2010. Our working capital at December 31, 2011 increased $71.6 million from December 31, 2010. This increase in working capital primarily resulted from a $75.5 million increase in our cash, cash equivalents and current marketable securities from December 31, 2010 to December 31, 2011. Additionally, prior year amounts have been reclassified to conform to the current year presentation.

(4) Under approved common stock repurchase plans, we repurchased and retired shares of common stock at an aggregate cost of $250.0 million, $99.9 million, $174.8 million, and $75.0 million in 2011, 2010, 2009 and 2008, respectively.

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

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility. Our molecular diagnostic products are designed to detect diseases more rapidly and/or accurately than older tests, and are among the fastest-growing categories of the IVD industry.

We market a broad portfolio of NATs to detect infectious microorganisms, including those causing STDs, tuberculosis, strep throat and other infections. Our leading clinical diagnostics products include our APTIMA family of assays that are used to detect the common STDs chlamydia and gonorrhea, certain high-risk strains of HPV and *Trichomonas vaginalis*, the parasite that causes trichomoniasis.

In recent years, we have expanded our portfolio of products with acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel in April 2009, offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse in October 2009 added a portfolio of real-time PCR products for detecting influenza and other infectious organisms. In addition, in December 2010 we acquired GTI Diagnostics, a manufacturer of certain of our transplant diagnostic products, as well as specialty coagulation and transfusion-related blood bank products.

In blood screening, we developed and manufacture the PROCLEIX family of assays, which are used to detect HIV-1, HCV, HBV and WNV in donated human blood. Our blood screening products are marketed worldwide by Novartis under Novartis trademarks. We were awarded a 2004 National Medal of Technology, the nation s highest honor for technological innovation, in recognition of our pioneering work in developing NAT testing systems to safeguard the blood supply in the United States.

Several of our current and future molecular tests can be performed on our TIGRIS instrument, a fully automated, high-throughput NAT system for diagnostics and blood screening. We are building on the success of our TIGRIS instrument system by commercializing our next-generation PANTHER instrument, which is a versatile, fully automated NAT system for low- to mid-volume laboratories. The PANTHER instrument was CE-marked and launched in Europe for diagnostic use in the fourth quarter of 2010. In addition, in May 2011 we filed a 510(k) application with the FDA for clearance of our PANTHER system to run our APTIMA Combo 2 assay for the detection of chlamydia and gonorrhea. In August 2011, Health Canada granted us a medical device license to use the PANTHER system to run our APTIMA Combo 2 assay in Canada. We are also developing the PANTHER system for use in the blood screening market as part of our blood screening collaboration with Novartis.

Our development pipeline includes products to detect:

certain genotypes of HPV, which can cause cervical cancer;

gene-based markers for prostate cancer;

Table of Contents

the quantity of certain viruses, often referred to as the viral load ;

certain gastrointestinal pathogens;

antigens and antibodies that are used to determine transplant and transfusion compatibility; and

coagulation disorders.

Recent Events

Financial results

Product sales for 2011 were $562.6 million, compared to $522.7 million in 2010, an increase of 8%. Total revenues for 2011 were $576.2 million, compared to $543.3 million in 2010, an increase of 6%. Net income for 2011 was $50.1 million ($1.04 per diluted share), compared to $106.9 million ($2.18 per diluted share) in 2010, a decrease of 53%. The decline in net income for 2011 was caused primarily by a $39.5 million ($0.82 per diluted share) OTTI loss we recorded in the third quarter of 2011 on our equity investment in Pacific Biosciences as well as goodwill and asset impairment charges of $12.7 million ($0.26 per diluted share) related to our acquired businesses recorded in the fourth quarter of 2011.

Our total revenues, net income and fully diluted earnings per share during 2011 included the results of operations of GTI Diagnostics for the entire year. In contrast, our total revenues, net income and fully diluted earnings per share during 2010 only included the results of operations of GTI Diagnostics from the date of our acquisition in December 2010.

FDA clearance of APTIMA Trichomonas assay

In April 2011, the FDA cleared our APTIMA Trichomonas vaginalis assay for sale and marketing in the United States. The APTIMA Trichomonas assay is an amplified nucleic acid test that detects *Trichomonas vaginalis*, the most common curable sexually transmitted infection in the United States. The APTIMA Trichomonas assay has been approved for use on our fully automated, high-throughput TIGRIS instrument system.

FDA approval of APTIMA HPV assay

In October 2011, the FDA approved our APTIMA HPV assay, an amplified nucleic acid test that detects certain high-risk strains of HPV that are associated with cervical cancer and precancerous lesions, for sale and marketing in the United States. The APTIMA HPV assay has been approved for use on our TIGRIS instrument system.

FDA approval of PROGENSA PCA3 assay

In February 2012, the FDA approved our PROGENSA PCA3 assay, a prostate cancer specific molecular diagnostic test, for sale and marketing in the United States. The PROGENSA PCA3 assay has been approved for use on our semi-automated DTS instrument systems.

Stock repurchase programs

In February 2011, our Board of Directors authorized the repurchase of up to $150.0 million of our common stock until December 31, 2011, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. We completed the program in August 2011, repurchasing and retiring approximately 2.5 million shares at an average price of $60.00 per share, or approximately $150.0 million in total.

Table of Contents

In September 2011, our Board of Directors authorized the repurchase of up to an additional $100.0 million of our common stock from November 2011 through June 2012, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. We completed the program in December 2011, repurchasing and retiring approximately 1.7 million shares at an average price of $58.83 per share, or approximately $100.0 million in total.

Results of Operations

Amounts and percentages in the following tables and throughout our discussion and analysis of financial condition and results of operations may reflect rounding adjustments. Percentages have been rounded to the nearest whole percentage.

Product sales

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Clinical diagnostics	$ 353.0	$ 305.8	$ 274.2	$ 47.2	15%	$ 31.6	12%
Blood screening	199.4	203.1	197.6	(3.7)	(2)%	5.5	3%
Research products and services	10.2	13.8	12.0	(3.6)	(26)%	1.8	15%
Total product sales	$ 562.6	$ 522.7	$ 483.8	$ 39.9	8%	$ 38.9	8%
As a percent of total revenues	98%	96%	97%				

Our primary source of revenue comes from product sales, which consist primarily of the sale of clinical diagnostics and blood screening products. Our clinical diagnostic product sales consist primarily of the sale of our women s health, other infectious disease, transplant diagnostics, and genetic testing products. The principal customers for our clinical diagnostics products include reference laboratories, public health institutions and hospitals. The blood screening assays and instruments we manufacture are marketed and distributed worldwide through our collaboration with Novartis under Novartis Procleix and Ultrio trademarks.

We recognize product sales from the manufacture and shipment of tests for screening donated blood at the contractual transfer prices specified in our collaboration agreement with Novartis for sales to end-user blood bank facilities located in countries where our products have obtained governmental approvals. Blood screening product sales are then adjusted monthly corresponding to Novartis payment to us of amounts reflecting our ultimate share of net revenue from sales by Novartis to end users, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Novartis to third parties, less freight, duty and certain other adjustments specified in our collaboration agreement with Novartis, multiplied by our share of the net revenue.

Product sales increased by 8% in 2011 compared to 2010. The increase was primarily attributed to higher sales from APTIMA assays and a full year of sales from our acquired GTI Diagnostics business, partially offset by lower research products and services and blood screening revenues. Product sales increased by 8% in 2010 compared to 2009. The increase was primarily attributed to higher APTIMA assay sales, contributions from our acquired companies, and higher blood screening revenues.

Clinical diagnostic product sales

Clinical diagnostic product sales, including assay, instrument, and ancillary sales, represented $353.0 million, or 63% of product sales in 2011, compared to $305.8 million, or 59% of product sales in 2010. The $47.2 million increase in clinical diagnostic product sales from 2010 to 2011 is primarily attributed to increased APTIMA sales, the inclusion of product sales of our acquired GTI Diagnostics business, and increased sales of transplant diagnostics and other infectious disease products.

Table of Contents

During 2011, clinical diagnostic product sales were positively affected by favorable estimated exchange rate impacts of $2.5 million as compared to the prior year, primarily due to a weaker U.S. dollar versus the Euro, Canadian dollar and British pound.

Clinical diagnostic product sales, including assay, instrument, and ancillary sales, represented $305.8 million, or 59% of product sales in 2010, compared to $274.2 million, or 57% of product sales in 2009. The $31.6 million increase in clinical diagnostic product sales from 2009 to 2010 is primarily attributed to customer conversion from our non-amplified PACE test to our amplified APTIMA test. In general, the price of our amplified APTIMA test is twice that of our non-amplified PACE product, thus the conversion from PACE to APTIMA drives an overall increase in product sales even if underlying testing volumes remain the same. The increase can also be attributed to additional sales by our acquired companies in 2010 compared to 2009.

During 2010, clinical diagnostic product sales were negatively affected by unfavorable estimated exchange rate impacts of $0.2 million as compared to the prior year, primarily due to a stronger U.S. dollar versus the Euro.

Blood screening product sales

Blood screening product sales, including assay, instrument, and ancillary sales, represented $199.4 million, or 35% of product sales in 2011, compared to $203.1 million, or 39% of product sales in 2010. The $3.7 million decrease in blood screening product sales from 2010 to 2011 is primarily attributed to decreased sales of blood screening-related instrumentation and assays to Novartis resulting from fluctuations in Novartis inventory levels, and lower net revenue payments received from Novartis.

During 2011, blood screening product sales were positively affected by favorable estimated exchange rate impacts of $2.7 million as compared to the prior year, primarily due to a weaker U.S. dollar versus the Euro.

Blood screening product sales, including assay, instrument, and ancillary sales, represented $203.1 million, or 39% of product sales in 2010, compared to $197.6 million, or 41% of product sales in 2009. The $5.5 million increase in blood screening product sales from 2009 to 2010 is primarily attributed to an increase in blood screening product demand from Novartis, the contractual increase in the net percentage share of revenues we receive from Novartis, as well as an increase in the sale of blood screening-related instrumentation. These factors were offset by $8.2 million of one-time revenue recognized during 2009 as a result of the renegotiation of our collaboration agreement with Novartis.

During 2010, blood screening product sales were negatively affected by unfavorable estimated exchange rate impacts of $0.8 million as compared to the prior year, primarily due to a stronger U.S. dollar versus the Euro.

Research products and services

As a result of our acquisition of Tepnel in April 2009, we have established an additional category of product sales, which we refer to as Research products and services. These sales represent outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies. Research products and services revenues were $10.2 million in 2011 compared to $13.8 million in 2010. The decrease from 2010 to 2011 is primarily due to continued market weakness affecting contract research organizations.

Research products and services revenues were $13.8 million in 2010 compared to $12.0 million in 2009. The increase from 2009 to 2010 is primarily due to an additional quarter of research products and services revenues that were not present in the prior year due to our acquisition of Tepnel in April 2009.

Table of Contents

Collaborative research revenue

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Collaborative research revenue	$ 7.7	$ 14.5	$ 7.9	$ (6.8)	(47)%	$ 6.6	84%
As a percent of total revenues	1%	3%	2%				

We recognize collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned, in relative proportion to the performance required under the contracts, or as reimbursable costs are incurred related to those agreements. Milestone consideration that is contingent upon achievement of a milestone in its entirety is recorded as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive.

The costs associated with collaborative research revenue are based on fully burdened full-time equivalent rates and are reflected in our consolidated statements of income under the captions Research and development, Marketing and sales and General and administrative, based on the nature of the costs. We do not separately track all of the costs applicable to our collaborations and, therefore, are not able to quantify all of the costs associated with collaborative research revenue.

Collaborative research revenue decreased 47% in 2011 compared to 2010. The $6.8 million decrease was primarily due to decreased reimbursements received from Novartis for shared development expenses attributable to the development of the PANTHER instrument and related product enhancements for use in the blood screening market.

Collaborative research revenue increased 84% in 2010 compared to 2009. The $6.6 million increase was primarily due to reimbursements from Novartis for shared development expenses attributable to the development of the PANTHER instrument and related product enhancements for use in the blood screening market.

Collaborative research revenue tends to fluctuate based on the type and amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative research revenue, results in any one period are not necessarily indicative of the results that will be achieved in the future. Our ability to generate additional collaborative research revenue depends, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners and the advancement of related collaborative research and development activities.

Royalty and license revenue

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Royalty and license revenue	$ 6.0	$ 6.1	$ 6.6	$ (0.1)	(2)%	$ (0.5)	(8)%
As a percent of total revenues	1%	1%	1%				

We recognize revenue for royalties due to us under license agreements with third parties upon the manufacture, sale or use of our products or technologies. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the applicable licensee. Non-refundable license fees with stand-alone value are recognized at the time that we have satisfied all performance obligations. License fees without stand-alone value are recognized in combination with any undelivered performance obligations.

Table of Contents

Royalty and license revenue decreased by 2% in 2011 as compared to 2010. The $0.1 million decrease was attributable to decreases in other license revenue offset by a slight increase in collaboration royalties received from Novartis related to the plasma testing market.

Royalty and license revenue decreased by 8% in 2010 as compared to 2009. The $0.5 million decrease was primarily a result of lower collaboration royalties received from Novartis related to the plasma testing market.

Royalty and license revenue may fluctuate based on the nature of the related agreements and the timing of receipt of license fees. Results in any one period are not necessarily indicative of results to be achieved in the future. In addition, our ability to generate additional royalty and license revenue will depend, in part, on our ability to market and commercialize our technologies.

Cost of product sales

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Cost of product sales	$ 173.6	$ 169.2	$ 152.4	$ 4.4	3%	$ 16.8	11%
Gross profit margin as a percent of product sales	69%	68%	69%				

Cost of product sales includes direct material, direct labor and manufacturing overhead associated with the production of inventories. Cost of product sales may fluctuate significantly in different periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales is also affected by manufacturing efficiencies, allowances for scrap or expired material, additional costs related to initial production quantities of new products after achieving FDA approval, instrument and software amortization, and contractual adjustments, such as instrumentation costs, instrument service costs, warranty costs and royalties. Cost of product sales excludes the amortization of acquisition-related intangibles.

In addition, we manufacture significant quantities of materials, development lots, and clinical trial lots of product prior to receiving approval from the FDA for commercial sale. The majority of costs associated with development lots are classified as R&D expense. The portion of a development lot that is manufactured for commercial sale is capitalized to inventory and classified as cost of product sales upon shipment.

Cost of product sales increased 3% in 2011 compared to 2010. The $4.4 million increase was primarily due to additional cost of sales related to our acquired GTI Diagnostics business and higher sales of our APTIMA products. These higher costs were partially offset by lower cost of product sales related to lower revenues from our research products and services business.

Our gross profit margin as a percentage of product sales increased to 69% in 2011 from 68% in 2010. The increase in gross profit margin as a percentage of product sales was principally attributed to increased sales of higher margin APTIMA and infectious disease products and decreased sales of lower margin instrumentation. Partially offsetting these increases was a decrease in blood screening net revenues received from Novartis.

Cost of product sales increased 11% in 2010 compared to 2009. The $16.8 million increase was primarily due to additional cost of product sales by our acquired companies and increases attributed to instrumentation, APTIMA, and blood screening product shipments. These higher costs were partially offset by favorable manufacturing variances related to changes in production volumes.

Our gross profit margin as a percentage of product sales decreased to 68% in 2010 from 69% in 2009. The decrease in gross profit margin as a percentage of product sales was principally attributed to lower gross margins

Table of Contents

in blood screening product sales as a result of an increase in test shipments as a proportion of our overall share of blood screening revenues, lower overall gross margin percentage at our acquired Tepnel businesses and increased sales of lower margin instrumentation. These decreases were partially offset by increased sales of higher margin APTIMA products.

A portion of our blood screening revenues is attributable to sales of TIGRIS and PANTHER instruments to Novartis, which totaled $13.0 million, $16.1 million and $15.9 million during 2011, 2010 and 2009, respectively. Under our collaboration agreement with Novartis, we sell instruments to Novartis at prices that approximate cost and share in profits of end-user sales in the United States. These instrument sales, therefore, negatively impact our gross margin percentage in the periods during which they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

Acquisition-related intangible amortization

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Acquisition-related intangible amortization	$ 11.1	$ 8.8	$ 4.1	$ 2.3	26%	$ 4.7	115%
As a percent of total revenues	2%	2%	1%				

Amortization expense related to our acquired intangible assets increased 26% in 2011 as compared to 2010. The $2.3 million increase was attributable to additional amortization expense resulting from our acquisition of GTI Diagnostics in December 2010.

Amortization expense related to our acquired intangible assets increased 115% in 2010 as compared to 2009. The $4.7 million increase was attributable to an additional three months of amortization expense resulting from our acquisition of Tepnel in April 2009 as well as an additional nine months of amortization expense resulting from our acquisition of Prodesse in October 2009.

Our acquired intangible assets are amortized using the straight-line method over their estimated useful lives, which range from 5 to 20 years.

Goodwill and asset impairment charges

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Goodwill and asset impairment charges	$ 12.7	$	$	$ 12.7	N/M	$	N/M
As a percent of total revenues	2%	%	%				

We assess the impairment of goodwill and intangible assets whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Goodwill impairment is reviewed at least annually at the reporting unit level, and occurs at the same time in the fourth quarter of each year, unless circumstances indicate that impairment has occurred before the fourth quarter of any given year.

In the fourth quarter of 2011, we recorded goodwill and intangible asset impairment charges totaling $12.7 million. Of the total charge, $8.7 million related to a goodwill impairment charge relating to Tepnel s European operations, which primarily consist of our research products and services business. Due to market weakness affecting contract research organizations, we reduced our revenue outlook for our research products and services business. As a result, our 2011 annual impairment test for goodwill indicated that the carrying value of Tepnel s European operations unit exceeded its fair value.

Table of Contents

Additionally, in the fourth quarter of 2011, we recorded an impairment charge of $4.0 million related to certain in-process research and development assets obtained as part of our acquisition of GTI Diagnostics in December 2010. We determined that the fair value of certain acquired in-process research and development assets had declined in value since the time of acquisition due to lower sales projections for these acquired assets.

Research and development

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Research and development	$ 112.7	$ 111.1	$ 106.0	$ 1.6	1%	$ 5.1	5%
As a percent of total revenues	20%	20%	21%				

We invest significantly in R&D as part of our ongoing efforts to develop new products and technologies. Our R&D expenses include the development of proprietary products and instrument platforms, as well as expenses related to the development of new products and technologies in collaboration with our partners. R&D spending is dependent on the status of projects under development and may vary substantially between quarterly or annual reporting periods.

R&D expenses increased 1% in 2011 from 2010. The $1.6 million increase was primarily related to the inclusion of R&D programs at our acquired GTI Diagnostics business, offset by a reduction in development expenses as a result of the wind-down of the clinical trials for our HPV, PCA3 and Trichomonas assays, and lower development costs resulting from the completion of our PANTHER instrument.

R&D expenses increased 5% in 2010 from 2009. The $5.1 million increase was primarily related to our acquired Tepnel and Prodesse businesses, partially offset by a decline in clinical trial expenses for our APTIMA HPV assay.

Marketing and sales

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Marketing and sales	$ 68.4	$ 59.5	$ 53.9	$ 8.9	15%	$ 5.6	10%
As a percent of total revenues	12%	11%	11%				

Our marketing and sales expenses include salaries and other personnel-related expenses, promotional expenses, and fees for outside services.

Marketing and sales expenses increased 15% in 2011 from 2010. The $8.9 million increase is primarily attributed to increases in headcount, personnel-related expenses, and marketing activities attributable to our acquired GTI Diagnostics business and continued investment in international expansion, primarily in Western Europe.

Marketing and sales expenses increased 10% in 2010 from 2009. The $5.6 million increase is primarily attributed to an increase in salaries, personnel-related expenses, and marketing activities due to our continued investment in international expansion, primarily in Western Europe, and our acquisition of Prodesse in October 2009.

Table of Contents

General and administrative

(Dollars in millions)	Years Ended December 31, 2011	2010	2009	2011/2010 $ Change	2011/2010 % Change	2010/2009 $ Change	2010/2009 % Change
General and administrative	$ 71.4	$ 56.8	$ 61.8	$ 14.6	26%	$ (5.0)	(8)%
As a percent of total revenues	12%	10%	12%				

Our general and administrative, or G&A, expenses include expenses for finance, legal, strategic planning and business development, public relations and human resources.

G&A expenses increased 26% in 2011 from 2010. The $14.6 million increase in 2011 is primarily attributable to higher G&A costs relating to litigation, patent prosecution and other professional services, costs associated with the consolidation of our United Kingdom operations and our acquired GTI Diagnostics business. In August 2010, we received a $2.9 million arbitration award for attorneys fees and costs related to our arbitration proceeding with Digene, which was recorded as a reduction of G&A expenses.

G&A expenses decreased 8% in 2010 from 2009. The $5.0 million decrease is primarily attributable to the receipt in August 2010 of a $2.9 million arbitration award for attorneys fees and costs related to our arbitration proceeding with Digene and lower G&A costs associated with our acquired Tepnel and Prodesse businesses. This decrease was partially offset by an increase in legal fees relating to our litigation with BD, and an increase in expenses related to the consolidation of our United Kingdom operations and costs associated with the acquisition of GTI Diagnostics.

Total other income, net

(Dollars in millions)	Years Ended December 31, 2011	2010	2009	2011/2010 $ Change	2011/2010 % Change	2010/2009 $ Change	2010/2009 % Change
Investment and interest income	$ 8.7	$ 11.8	$ 21.6	$ (3.1)	(26)%	$ (9.8)	(45)%
Interest expense	(2.1)	(2.2)	(1.9)	0.1	(5)%	(0.3)	16%
Gain on contingent consideration		8.0		(8.0)	N/M	8.0	N/M
Other-than-temporary impairment loss on equity investment	(39.5)			(39.5)	N/M		N/M
Other income (expense), net	(0.2)	(0.2)			%	(0.2)	N/M
Total other income, net	$ (33.1)	$ 17.4	$ 19.7	$ (50.5)	(290)%	$ (2.3)	(12)%

Investment and interest income

The $3.1 million decrease in investment and interest income during 2011 as compared to the prior year is primarily attributed to decreased interest income from lower investment balances in 2011 as a result of the sale of investments to fund our stock repurchase programs and recent acquisitions, and lower net realized gains on sales of marketable securities.

The $9.8 million decrease in investment and interest income during 2010 as compared to the prior year is primarily attributed to lower net realized gains on sales of marketable securities, decreased interest income due to lower investment balances in 2010 as a result of the sale of investments to fund our recent acquisitions, cash used for our stock repurchase program, and higher purchase premium amortizations arising from increased market demand for tax-advantaged municipal bonds.

Table of Contents

Interest expense

Interest expense decreased by $0.1 million, or 5%, from 2010 to 2011. The decrease is primarily attributable to lower interest rates during 2011 on our credit facility with Bank of America.

Interest expense increased by $0.3 million, or 16% from 2009 to 2010. The increase is primarily attributable to a full year of interest expense in 2010 on our credit facility with Bank of America, which we entered into in February 2009 to fund our acquisition of Tepnel and for other general corporate purposes.

Gain on contingent consideration

We recorded a non-cash gain of $8.0 million in 2010 as a result of a reduction in the fair value of the contingent consideration liability related to our acquisition of Prodesse. The fair value of the contingent consideration liability was reduced to $0 as of December 31, 2010, because we did not expect to make any further milestone payments related to our acquisition of Prodesse. All contingent obligations relating to our acquisition of Prodesse have lapsed as of December 31, 2011, with no additional amounts due.

Other-than-temporary impairment loss on equity investment

In June 2010, we purchased $50.0 million of Pacific Biosciences Series F preferred stock as a participant in Pacific Biosciences Series F preferred stock financing, which raised a total of approximately $109.0 million. In October 2010, Pacific Biosciences completed an initial public offering of its common stock at a price of $16.00 per share, which now trades on the NASDAQ Global Select Market under the symbol PACB. As a result of the initial public offering, our preferred stock was converted into common stock with a basis of $15.26 per share.

In the third quarter of 2011, Pacific Biosciences share price declined from $12.00 per share on July 1 to $3.21 per share on September 30. The share prices of other publicly-traded sequencing companies also declined during the third quarter due to market conditions. As of September 30, 2011, the trading price of the Pacific Biosciences common stock had declined by approximately 80% from the original cost basis of our investment and our Pacific Biosciences common stock had been in an unrealized loss position for approximately seven months.

The determination of whether a decline in value is other-than-temporary is, in part, subjective and influenced by many factors. We considered various factors in determining whether the impairment was deemed to be other-than-temporary, including the near-term and long-term prospects of Pacific Biosciences, the length of time and relative magnitude of the price decline, the general and industry-specific market conditions affecting Pacific Biosciences, the views of external investment analysts, and our intent and ability to hold the investment until the price recovers.

Based on our consideration of the relevant accounting guidance and because the trading price of the Pacific Biosciences common stock may remain below our cost basis for an extended period of time, we recognized a $39.5 million OTTI loss in the third quarter of 2011 related to our investment in Pacific Biosciences, even though the market price of Pacific Biosciences common stock may recover over time.

We originally invested in Pacific Biosciences with a long-term horizon and continue to possess the intent and ability to hold this investment for the long-term. In addition to our investment, we are collaborating with Pacific Biosciences in the development of third generation sequencing systems for *in vitro* diagnostics. We believe that third generation sequencing technology offers multiple advantages over earlier methods, including lower cost and greater speed. Despite the recent decline in the trading price of Pacific Biosciences common stock, we continue to believe that significant value exists within Pacific Biosciences related to third generation sequencing technology, especially as it may be applied to the diagnostics market.

Table of Contents

Other income (expense), net

Other income (expense), net remained constant in 2011 from 2010. The net increase of $0.2 million in 2010 to 2009 was primarily attributable to exchange rate impacts.

Income tax expense

	Years Ended December 31,			2011/2010		2010/2009	
(Dollars in millions)	2011	2010	2009	$ Change	% Change	$ Change	% Change
Income tax expense	$ 43.0	$ 48.3	$ 48.0	$ (5.3)	(11)%	$ 0.3	1%
As a percent of income before tax	46%	31%	34%				

Our income tax expense decreased 11% in 2011 as compared to the prior year. The $5.3 million decrease was attributable to lower 2011 pre-tax earnings, which included the OTTI loss on our equity investment in Pacific Biosciences and goodwill and acquired intangible asset impairment charges. Pre-tax earnings for 2010 included gains on contingent consideration. Additionally, income tax expense declined due to lower 2011 California taxes resulting from a change in California tax laws. Our tax expense in 2011 included a $14.6 million valuation allowance for the OTTI loss as our ability to utilize that loss depends on the timing and nature of future events which we cannot reasonably predict at this time. As a result of our 2011 goodwill impairment charge and our 2010 gains on contingent consideration not being taxable, our effective tax rate increased by 15% from 2010 to 2011.

Our effective tax rate in 2010 decreased from 2009 primarily due to the expiration of statutes of limitations for past tax returns, contingent consideration adjustments in 2010 that are generally not taxable, and a statutory increase in U.S. domestic manufacturing tax benefits, offset by the negative impact of lower tax advantaged interest income.

Liquidity and capital resources

(Dollars in millions)	December 31, 2011	December 31, 2010
Cash, cash equivalents and current marketable securities	$ 305.8	$ 230.3
Working capital	164.9	93.3
Current ratio	1.5:1	1.3:1

Our working capital as of December 31, 2011 increased $71.6 million from December 31, 2010. This increase in working capital during the year can be primarily attributed to increases in current marketable securities, cash and cash equivalents, and inventories which totaled $48.1 million, $27.3 million, and $11.5 million, respectively. Offsetting these increases was an increase during the year in our short-term borrowings of $8.0 million under our credit facility.

The primary objectives of our investment policy are liquidity and safety of principal. Consistent with these objectives, investments are made with the goal of achieving the highest rate of return. The policy places emphasis on securities of high credit quality, with restrictions placed on maturities and concentration by security type and issue.

Our marketable securities include equity securities, mutual funds, treasury securities, tax advantaged municipal securities and FDIC insured corporate bonds. Our investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years with a minimum Moody s credit

Table of Contents

rating of A3 or a Standard & Poor s credit rating of A-. As of December 31, 2011, our portfolios had an average maturity of three years and an average credit quality of AA1 as defined by Moody s.

(Dollars in millions)	Years Ended December 31, 2011	2010	2009	$ Change 2011/2010	$ Change 2010/2009
Cash provided by (used in):					
Operating activities	$ 181.3	$ 169.6	$ 145.0	$ 11.7	$ 24.6
Investing activities	36.9	(114.5)	(198.4)	151.4	83.9
Financing activities	(188.6)	(75.9)	74.8	(112.7)	(150.7)
Purchases of property, plant and equipment (included in investing activities above)	(41.7)	(30.7)	(32.4)	(11.0)	1.7

Our primary source of liquidity has been cash from operations, which includes the collection of accounts and other receivables related to product sales, collaborative research agreements, and royalty and license fees. Additionally, our liquidity was enhanced in 2009 by our credit facility with Bank of America, described in Note 10 Borrowings, of the Notes to the Consolidated Financial Statements included elsewhere in this Annual Report. Our primary short-term cash needs, which are subject to change, include continued R&D spending to support new products, costs related to commercialization of products and purchases of instrument systems for placement with our customers. In addition, we may use cash for strategic purchases which may include the acquisition of businesses and/or technologies complementary to our business and for stock repurchase programs. Certain R&D costs may be funded under collaboration agreements with our collaboration partners.

Operating activities provided net cash of $181.3 million during 2011, primarily from net income of $50.1 million and non-cash charges to net income of $131.2 million. Non-cash charges primarily consisted of an OTTI loss on our equity investment in Pacific Biosciences of $39.5 million, stock-based compensation expense of $24.7 million, depreciation of $25.6 million, amortization of intangibles of $21.0 million and goodwill and asset impairment charges of $12.7 million. The $11.7 million increase in cash from operating activities from 2010 to 2011 was primarily due to higher non-cash charges in 2011 and a decrease in our long-term assets in 2011, partially offset by an increase in our inventory levels in 2011.

Net cash provided by investing activities during 2011 was $36.9 million. We received $94.1 million in net proceeds from the sale and maturities of marketable securities, which was offset by purchases of property, plant and equipment of $41.7 million, purchases of capitalized software of $6.1 million, purchases of intangible assets, including license fees, of $5.3 million, and a $4.0 million investment in Roka. The $151.4 million increase in cash from investing activities from 2010 to 2011 was primarily due to a $50.0 million payment in 2010 for our investment in Pacific Biosciences, a $53.0 million payment in 2010 for our acquisition of GTI Diagnostics, and an additional $67.7 million of net proceeds in 2011 from the sales and maturities of our marketable securities.

Net cash used in financing activities during 2011 was $188.6 million, primarily driven by $250.0 million used to repurchase and retire approximately 4.2 million shares of our common stock under our 2011 stock repurchase programs. This use of cash was offset by $49.9 million in proceeds from the issuance of our common stock under equity incentive and employee stock purchase plans, and $8.0 million in additional net borrowings under our credit facility. The $112.7 million decrease in cash from financing activities from 2010 to 2011 was primarily due to an additional $150.0 million spent in 2011 repurchasing shares of our common stock, an $18.1 million increase in net proceeds from stock issuances in 2011, and a $10.0 million contingent consideration payment made in 2010 in connection with our acquisition of Prodesse.

We believe that our available cash balances, anticipated cash flows from operations, proceeds from stock option exercises and borrowings under our revolving credit facility will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt

Table of Contents

securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, or at all. Further, debt financing may subject us to covenants restricting our operations. Because our current credit facility is secured by our marketable debt securities, any significant needs for cash may cause us to liquidate some or all of our marketable debt securities resulting in the need to partially or completely pay down or refinance this indebtedness.

Contractual obligations and commercial commitments

Our contractual obligations due for purchase commitments, collaborative agreements and minimum royalties as of December 31, 2011 were as follows (in millions):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Material purchase commitments[1]	$ 63.5	$ 51.1	$ 9.8	$ 2.6	$
Operating leases[2]	30.6	3.2	5.4	2.8	19.2
Collaborative commitments[3]	2.7	0.9	1.0	0.8	
Minimum royalty commitments[4]	16.2	1.8	4.2	3.2	7.0
Deferred employee compensation[5]	4.9	0.7	1.9	1.2	1.1
Capital leases[6]	0.2	0.1	0.1		
Credit facility, including accrued interest[7]	248.2	248.2			
Total[8]	$ 366.3	$ 306.0	$ 22.4	$ 10.6	$ 27.3

(1) Amounts represent our minimum purchase commitments for instruments and raw materials from key vendors. Of the $63.5 million total, we have commitments from third-parties to purchase $12.8 million of instruments.

(2) Reflects obligations for facilities and vehicles under operating leases in place as of December 31, 2011. Future minimum lease payments are included in the table above.

(3) In addition to the minimum payments due under our collaborative agreements included in the table above, we may be required to pay up to $4.8 million in milestone payments, plus royalties on net sales of any products using specified technology.

(4) Amounts represent our minimum royalties due on the net sales of products incorporating licensed technology and subject to a minimum annual royalty payment. During 2011, we recorded $9.6 million in royalty costs related to our various license agreements.

(5) The $4.9 million represents deferred compensation plan liabilities for in-service distributions. Our total deferred compensation plan liability as of December 31, 2011 was $6.1 million, which includes the $4.9 million included in the table above and $1.2 million due to employees upon retirement. We have excluded the amount payable upon employee retirement from the table above as we cannot reasonably predict when such retirement events may occur.

(6) Reflects obligations on capital leases in place as of December 31, 2011. Interest amounts were not material; therefore, capital lease obligations are shown net of interest expense in the table above.

(7)

As of December 31, 2011, the total principal amount outstanding under our revolving credit facility with Bank of America was $248.0 million. The term of this credit facility is due to expire in February 2013. Interest payable on this outstanding amount included in the table above has been estimated based on the interest rate payable at December 31, 2011, which was approximately 0.88%. In addition, we are required to pay a commitment fee on funds available for borrowing under the credit facility, which has also been estimated for the remaining term of the credit facility based on the fixed-rate of 0.25% as of December 31, 2011.

(8) Does not include amounts relating to our obligations under our collaboration with Novartis, pursuant to which both parties have obligations to each other. Under our collaboration agreement with Novartis, we are

Table of Contents

obligated to manufacture and supply blood screening assays to Novartis, and Novartis is obligated to purchase all of the assay quantities specified on a 90-day demand forecast, due 90 days prior to the date Novartis intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

Liabilities associated with uncertain tax positions, currently estimated at $10.0 million (including interest), are not included in the table above as we cannot reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

Critical accounting policies and estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. 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 the related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectability of accounts receivable, valuation of inventories and long-lived assets, including license and manufacturing access fees, patent costs and capitalized software, equity investments in publicly and privately held companies, accrued liabilities, income tax and the valuation of stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

The following critical accounting policies affect the significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

We record shipments of our clinical diagnostic products as product sales when the product is shipped, title and risk of loss have passed to the customer, the consideration is fixed and determinable, and collection of the resulting receivable is reasonably assured.

We manufacture blood screening products according to demand schedules provided by our collaboration partner, Novartis. Upon shipment to Novartis, we recognize blood screening product sales at an agreed upon transfer price and record the related cost of products sold. Based on the terms of our collaboration agreement with Novartis, our ultimate share of the net revenue from sales to the end user is not known until reported to us by Novartis. We then adjust blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting our ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized.

In most cases, we provide our instrumentation to our clinical diagnostics customers without requiring them to purchase the equipment or enter into an equipment lease. Instead, we recover the cost of providing the instrumentation in the amount we charge for our diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

We sell our instruments to Novartis for use in blood screening and record these instrument sales upon delivery since Novartis is responsible for the placement, maintenance and repair of the units with its customers. We also sell instruments to our clinical diagnostics customers and record sales of these instruments upon delivery and customer acceptance. For certain customers with non-standard payment terms, instrument sales are recorded

Table of Contents

based upon expected cash collection. Prior to delivery, each instrument is tested to meet our specifications and the specifications of the FDA, and is shipped fully assembled. Customer acceptance of our clinical diagnostic instrument systems requires installation and training by our technical service personnel. Installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation.

We record revenue on our research products and services in the period during which the related costs are incurred or the services are provided. This revenue consists of outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

We recognize collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the applicable contracts. Non-refundable license fees with stand-alone value are recognized at the time that we have satisfied all performance obligations. License fees without stand-alone value are recognized in combination with any undelivered performance obligations.

Royalty and license revenue is recognized related to the sale or use of our products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the applicable licensee.

Income taxes

Our income tax returns are based on calculations and assumptions that are subject to examination by various tax authorities. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of these examinations and any future examinations in determining the adequacy of our provision for income taxes. As part of our assessment of potential adjustments to our tax returns, we increase our tax liabilities or decrease our deferred tax assets to the extent a tax position taken on our return is not more likely than not to be sustained based upon its technical merits. We review, at least quarterly, the likelihood and amount of potential adjustments and adjust the income tax provision, the current tax liability and deferred taxes in the period in which credible new information causes us to change our assessment of the likelihood of a tax position being sustained. Although we believe that the estimates and assumptions supporting our assessments are reasonable, adjustments could be materially different from those that are reflected in historical income tax provisions and recorded assets and liabilities.

We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical taxable income, projected future taxable income, the expected timing of the reversals of existing temporary differences and the implementation of tax-planning strategies. In the event we were to determine that we would not be able to realize all or part of our deferred tax assets in the future, we would increase the valuation allowance and make a corresponding charge to earnings in the period in which we make such determination. Similarly, if we later determine that we are more likely than not to realize the deferred tax assets, we would reverse the applicable portion of the previously provided valuation allowance. In order for us to realize our deferred tax assets, we must be able to generate sufficient taxable income in the tax jurisdictions in which the deferred tax assets are located.

Stock-based compensation

We use the Black-Scholes-Merton option pricing model to value stock options granted. Stock-based compensation expense for restricted stock, deferred issuance restricted stock and performance stock awards is

Table of Contents

measured based on the closing fair market value of our common stock on the date of grant. Stock-based compensation expense for market condition stock awards is measured based on the fair value of the award on the date of grant using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple point variables that determine the probability of satisfying the market condition stipulated in the grant and calculates the fair value of the award.

Certain of these costs are capitalized into inventory on our consolidated balance sheets, and are recognized as an expense when the related products are sold.

Fair value measurements

We determine the fair value of our assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants as of the measurement date. There is an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the factors market participants would use in valuing the asset or liability.

Assets and liabilities are classified based upon the lowest level of input that is significant to the fair value measurement. The carrying amounts of financial instruments such as cash equivalents, accounts receivable, prepaid and other current assets, accounts payable and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. We review the fair value hierarchy on a quarterly basis. Changes in the observations or valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

Our cash equivalents and marketable securities include equity securities, mutual funds, treasury securities, tax advantaged municipal securities, Federal Deposit Insurance Corporation, or FDIC, insured corporate bonds and money market funds. When available, we use quoted market prices to determine fair value, which currently include our equity securities and mutual funds. We obtain the fair value of our marketable debt securities from a professional pricing service, which may determine the fair value using quoted prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals. We validate the fair value of our marketable debt securities provided by our professional pricing service by evaluating the reasonableness of the methods and assumptions used by the professional pricing service, and by comparing their assessment of the fair value of our investment portfolio against the fair value of our investment portfolio from an independent professional pricing source and with publicly available data for actual transactions.

Marketable securities

Our marketable securities include equity securities, mutual funds, treasury securities, tax advantaged municipal securities and FDIC insured corporate bonds. The primary objectives of our marketable debt security investment portfolio are liquidity and safety of principal. Investments are made with the goal of achieving the highest rate of return consistent with these two objectives. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

All of our marketable securities, except for the mutual funds, are classified as available-for-sale securities. The mutual funds are classified as trading securities. Marketable debt and equity securities classified as available-for-sale are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity under the caption Accumulated other comprehensive income (loss) on our

Table of Contents

consolidated balance sheets. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in Investment and interest income. The mutual funds are carried at fair value, with unrealized gains and losses included in Investment and interest income on our consolidated statements of income.

We periodically review our marketable securities for other-than-temporary declines in fair value below their cost basis, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. When assessing marketable debt and equity securities for other-than-temporary declines in value, we consider factors including: the significance of the decline in value compared to the cost basis; the underlying factors contributing to a decline in the prices of securities in a single asset class; how long the market value of the investment has been less than its cost basis; any market conditions that impact liquidity; the views of external investment analysts; the financial condition and near-term prospects of the investee; any news or financial information that has been released specific to the investee; and the outlook for the overall industry in which the investee operates.

We do not consider our investments in marketable debt securities with a current unrealized loss position to be other-than-temporarily impaired at December 31, 2011 because we do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at December 31, 2011 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of current portion on our consolidated balance sheets, reflecting our intent and ability to hold such investments to maturity.

Valuation of inventories

We record valuation adjustments to our inventory balances for estimated excess and obsolete inventory equal to the difference between the cost of such inventory and its usage which is based upon assumptions about future product demand and the shelf-life and expiration dates for finished goods and materials used in the manufacturing process. We operate in an environment that is regulated by the FDA and other governmental agencies that may place restrictions on our ability to sell our products if certain compliance requirements are not met. We have made assumptions that are reflected in our net inventory value based on information currently available to us. If future product demand, regulatory constraints or other market conditions are less favorable than those projected by management, additional inventory valuation reserves may be required.

We also manufacture products to conduct developmental evaluations and clinical trials, and to validate our manufacturing practices prior to receiving regulatory clearance for commercial sale of our products. In these circumstances, uncertainty exists regarding our ability to sell these products until the FDA or other governing bodies commercially approve them. Accordingly, the manufacturing costs of these items in inventory are recorded as R&D expense. In cases where we maintain current approved products for further development evaluations, we may also provide valuation allowances for these inventories due to the historical uncertainties associated with regulated product introductions into other markets. To the extent any of these products are sold to end users, we record revenues and reduce inventory reserves that are directly applicable to such products.

Gross inventory totaled $87.6 million and the allowance for excess and obsolete inventory was $9.7 million as of December 31, 2011. For 2011, 2010, and 2009, changes in our excess and obsolete inventory reserve have not materially affected our gross profit margin as a percentage of product sales.

Valuation of goodwill and intangible assets

Our business acquisitions typically result in the recording of goodwill and other intangible assets, and the recorded values of those assets may become impaired in the future. We also acquire intangible assets in other types of transactions. As of December 31, 2011, our goodwill and intangible assets (excluding capitalized

Table of Contents

software), net of accumulated amortization, were $140.4 million and $156.3 million, respectively. Of the $140.4 million of goodwill, $62.0 million, $33.0 million and $26.8 million relate to the acquisitions of Tepnel, Prodesse and GTI Diagnostics, respectively.

The determination of the value of such intangible assets requires management to make estimates and assumptions that affect our consolidated financial statements. For intangible assets purchased in a business combination, the estimated fair values of the assets acquired are used to establish their recorded values. Valuation techniques consistent with the market approach, income approach and/or cost approach are used to measure fair value. An estimate of fair value can be affected by many assumptions which require significant judgment. For example, the income approach requires assumptions related to the appropriate business model to be used to estimate cash flows, total addressable market, pricing and share forecasts, competition, technology obsolescence, future tax rates and discount rates. Our estimate of the fair value of certain assets, or our conclusion that the value of certain assets is not reliably estimable, may differ materially from determinations made by others who use different assumptions or utilize different valuation models. New information may arise in the future that affects our fair value estimates and could result in adjustments to our estimates in the future, which could have an adverse impact on our results of operations.

We assess the impairment of goodwill and intangible assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Goodwill impairment is reviewed at least annually at the reporting unit level, and occurs at the same time in the fourth quarter of each year, unless circumstances indicate that impairment has occurred before the fourth quarter of any given year. We utilize a discounted cash flow analysis to estimate the fair value of each reporting unit. The evaluation includes management estimates of cash flow projections based on an internal strategic review. Key assumptions from this strategic review include revenue growth, gross and operating margin growth, and our weighted average cost of capital. We use specific discount rates to determine the estimated value of each reporting unit. If actual results are not consistent with our estimates and assumptions used in estimating future cash flows and asset fair values, we may be exposed to losses that could be material.

Factors we consider important that could trigger impairment include the following:

- significant under performance relative to historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends;
- significant declines in our stock price for a sustained period; and
- decreased market capitalization relative to net book value.

When there is an indication that the carrying value of goodwill or an intangible asset may not be recoverable based upon the existence of one or more of the above indicators or other factors, an impairment loss is recognized if the carrying amount exceeds its fair value. Any resulting impairment loss could have an adverse impact on our operating expenses.

In the fourth quarter of 2011, we recorded goodwill and intangible asset impairment charges totaling $12.7 million. Of the total charge, $8.7 million related to goodwill associated with the European operations of Tepnel, which we acquired in April 2009. Tepnel s European operations primarily represent our research products and services business. Due to market weakness affecting contract research organizations, we reduced our revenue outlook for our research products and services business. As a result, our 2011 annual impairment test for goodwill indicated that the European operations unit carrying value exceeded its fair value. For further information, see Note 2 of the Notes to Consolidated Financial Statements included elsewhere in this Annual Report.

Table of Contents

Additionally, in the fourth quarter of 2011, we recorded an impairment charge of $4.0 million related to certain in-process research and development assets obtained as part of our acquisition of GTI Diagnostics in December 2010. We determined that the fair value of certain acquired in-process research and development assets had declined in value since the time of acquisition due to lower sales projections for such acquired assets. For further information, see Note 2 of the Notes to Consolidated Financial Statements included elsewhere in this Annual Report.

All of the in-process research and development projects that remain in development are subject to the inherent risks and uncertainties in product development. It is possible that we will not be able to successfully develop and complete the in-process research and development programs and profitably commercialize the underlying product candidates. If certain of the in-process research and development programs fail or are abandoned during development, we will not realize the future cash flows we estimated as part of our recent impairment review.

Capitalized software costs

We capitalize costs incurred in the development of computer software related to products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product or ten years.

As of December 31, 2011, capitalized software development costs totaled $17.0 million, net of accumulated amortization. Of that total, $16.4 million related to products for use on our TIGRIS and PANTHER instruments, which we began amortizing on a straight-line basis over 120 months in May 2004 and December 2010, respectively, coinciding with the general release of the instruments to our customers.

Recent accounting pronouncements

For information on the recent accounting pronouncements impacting our business, see Note 1 of the Notes to Consolidated Financial Statements included elsewhere in this Annual Report.

Off-Balance Sheet Arrangements

We do not currently have and have never had any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our investment portfolio and the amount of interest payable on our senior secured revolving credit facility with Bank of America. As of December 31, 2011, the total principal amount outstanding under the revolving credit facility was $248.0 million. At our option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America s prime rate and (iii) the London Interbank Offered Rate, or LIBOR, plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by us. We do not believe that we are exposed to significant interest rate risk with respect to our credit facility based on our option to select the rate at which interest accrues under the credit facility, the short-term nature of the

Table of Contents

borrowings and our ability to pay off the outstanding balance in a timely manner if the applicable interest rate under the credit facility increases above the current interest rate yields on our investment portfolio. A 100 basis point increase or decrease in interest rates would increase or decrease our interest expense by approximately $2.5 million on an annual basis.

Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in investment grade securities with an average portfolio maturity of no more than three years. A 25 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately $1.7 million on an annual basis. While changes in interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our consolidated statements of income until the investment is sold or if a reduction in fair value is determined to be other-than-temporary.

Equity Price Risk

We have minimal exposure to price fluctuations on mutual fund investments within our trading portfolio. The trading securities represent all of the assets held in trust under our deferred compensation plan. A corresponding liability is included within our current and non-current liabilities on the consolidated balance sheets. These investments are recorded at fair value with unrealized gains and losses recognized in our consolidated statements of income.

In connection with a collaboration agreement we entered into with Pacific Biosciences in June 2010, we purchased $50.0 million of Pacific Biosciences Series F preferred stock as a participant in Pacific Biosciences Series F preferred stock financing, which raised a total of approximately $109.0 million. In October 2010, Pacific Biosciences completed an initial public offering of its common stock at a price of $16.00 per share, and the stock now trades on the NASDAQ Global Select Market under the symbol PACB. As a result of the initial public offering, our Pacific Biosciences preferred stock was converted into common stock.

We originally recorded our $50.0 million investment in Pacific Biosciences preferred stock on a cost basis in our consolidated financial statements. Since Pacific Biosciences completed its initial public offering, our investment in Pacific Biosciences has been marked to fair market value each reporting period. We periodically review our marketable equity securities for other-than-temporary declines in fair value below their cost basis, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. In the third quarter of 2011, we recorded a $39.5 million OTTI loss on our investment in Pacific Biosciences. As of December 31, 2011, our investment in Pacific Biosciences had a fair market value of $9.2 million.

Our investment in Pacific Biosciences is subject to market price volatility. Fluctuations in the market price of publicly traded securities may result from perceived changes in the underlying economic characteristics of the issuer, the relative price of alternative investments, general market conditions and other factors.

A ten percent increase or decrease in the fair value of our investment in Pacific Biosciences would result in an increase or decrease to the fair value of our investment of approximately $0.9 million. Because the market price for our investment in Pacific Biosciences is subject to ongoing fluctuation, the amount we may eventually realize from a subsequent sale of our investment may differ significantly from the reported market value.

Foreign Currency Exchange Risk

Although the majority of our revenue is realized in U.S. dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. We translate the financial statements

Table of Contents

of our non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates in intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders equity under the caption Accumulated other comprehensive income (loss). These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Under our collaboration agreement with Novartis, a growing portion of blood screening product sales is from western European countries. As a result, our international blood screening product sales are affected by changes in the foreign currency exchange rates of those countries where Novartis business is conducted in Euros or other local currencies. Based on international blood screening product sales during 2011, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.6 million annually. Similarly, a 10% movement of currency exchange rates would also result in a clinical diagnostic product sales increase or decrease of approximately $5.6 million annually. A 10% movement of currency exchange rates would result in a research products and services sales increase or decrease of approximately $1.0 million annually. The majority of our collaborative research revenues and royalty and license revenues are denominated in U.S. dollars and, as such, are not subject to exchange rate exposure. Our exposure for both blood screening and clinical diagnostic product sales is primarily in the U.S. dollar versus the Euro, British pound, Australian dollar and Canadian dollar.

Our total payables denominated in foreign currencies as of December 31, 2011 were not material. Our receivables by currency as of December 31, 2011 reflected in U.S. dollar equivalents were as follows (in millions):

U.S. dollar	$ 45.4
Euro	6.1
British pound	3.2
Canadian dollar	1.7
Australian dollar	1.2
Other	0.5
Total gross trade accounts receivable	$ 58.1

In order to reduce the effect of foreign currency fluctuations, from time to time we have used foreign currency forward contracts, or forward contracts, to hedge certain foreign currency transaction exposures. Specifically, we entered into forward contracts with a maturity of approximately 30 days to hedge against the foreign exchange exposure created by certain balances that were denominated in a currency other than the principal reporting currency of the entity recording the transaction. These types of forward contracts do not qualify for hedge accounting and, accordingly, all of these instruments are marked to market at each balance sheet date by a charge to earnings. The gains and losses on such forward contracts are meant to mitigate the gains and losses on outstanding foreign currency transactions. We believe that such forward contracts, when used, do not subject us to undue risk due to foreign exchange movements because gains and losses on these contracts are generally offset by losses and gains on the underlying assets and liabilities. We do not use derivatives for trading or speculative purposes.

We did not enter into any foreign currency forward contracts during 2011.

Item 8. ***Financial Statements and Supplementary Data***

Our consolidated financial statements and the Reports of Ernst & Young LLP, our Independent Registered Public Accounting Firm, are included in this Annual Report on Form 10-K in Item 9A below and on pages F-1 through F-47.

Table of Contents

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

None.

Item 9A. ***Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our current and periodic reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In addition, the design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, 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, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2011.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011 based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2011.

Table of Contents

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2011. This report, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2011, is included elsewhere herein.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

Gen-Probe Incorporated:

We have audited Gen-Probe Incorporated s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Gen-Probe Incorporated 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 Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, Gen-Probe Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2011 and 2010, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2011 and our report dated February 23, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 23, 2012

Table of Contents

Item 9B. ***Other Information***
None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions Information Regarding the Board of Directors and Corporate Governance, Executives and Section 16(a) Beneficial Ownership Reporting Compliance contained in the Proxy Statement to be filed in connection with our 2012 Annual Meeting of Stockholders, or the Proxy Statement.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Ethics. The Code of Ethics is available on our website at http://www.gen-probe.com. If we make any substantive amendments to the Code of Ethics or grant any waiver from a provision of the Code of Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. Stockholders may request a free copy of the Code of Ethics from:

Gen-Probe Incorporated

Attention: Investor Relations

10210 Genetic Center Drive

San Diego, CA 92121-4362

(858) 410-8000

http://www.gen-probe.com

Item 11. ***Executive Compensation***
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions Executive Compensation, Compensation Committee Interlocks and Insider Participation and Compensation Committee Report contained in the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information contained in the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***
The information required by this Item is incorporated in this Annual Report by reference from the information under the captions Certain Related-Person Transactions, Related-Person Transactions Policy and Procedures and Information Regarding the Board of Directors and Corporate Governance contained in the Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions Principal Accountant Fees and Services and Pre-Approval Policies and Procedures contained in the Proxy Statement.

Table of Contents

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) *Documents filed as part of this report.*

1. The following financial statements of Gen-Probe Incorporated and Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in this report:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2011 and 2010

Consolidated Statements of Income for each of the three years in the period ended December 31, 2011

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2011

Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2011

Notes to Consolidated Financial Statements

2. Financial statement schedules.

Schedule II Valuation and Qualifying Accounts for each of the three years in the period ended December 31, 2011

All other schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or related notes.

3. List of Exhibits required by Item 601 of Regulation S-K.

See Item 15(b) below

(b) *Exhibits.*

See the Exhibit Index immediately following our consolidated financial statements and related schedule and the Exhibits filed or furnished in connection with this report.

Table of Contents

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.

GEN-PROBE INCORPORATED

By: /s/ Carl W. Hull
Carl W. Hull
Chairman and Chief Executive Officer (Principal Executive Officer)

Date: February 23, 2012

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/ Carl W. Hull Carl W. Hull	Chairman and Chief Executive Officer (Principal Executive Officer)	February 23, 2012
/s/ Herm Rosenman Herm Rosenman	Senior Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 23, 2012
/s/ John W. Brown John W. Brown	Director	February 23, 2012
/s/ Armin M. Kessler Armin M. Kessler	Director	February 23, 2012
/s/ John C. Martin John C. Martin, Ph.D.	Director	February 23, 2012
/s/ Phillip M. Schneider Phillip M. Schneider	Director	February 23, 2012
/s/ Lucy Shapiro Lucy Shapiro, Ph.D.	Director	February 23, 2012
/s/ Abraham D. Sofaer Abraham D. Sofaer	Director	February 23, 2012

/s/ Patrick J. Sullivan		Director	February 23, 2012

Patrick J. Sullivan

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED FINANCIAL STATEMENTS

CONTENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

Gen-Probe Incorporated:

We have audited the accompanying consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2011 and 2010, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2011. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and the financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gen-Probe Incorporated at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Gen-Probe Incorporated s internal control over financial reporting as of December 31, 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 February 23, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 23, 2012

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents, including restricted cash of $38 and $16 at December 31, 2011 and December 31, 2010, respectively	$ 87,021	$ 59,690
Marketable securities	218,789	170,648
Trade accounts receivable, net of allowance for doubtful accounts of $320 and $355 at December 31, 2011 and December 31, 2010, respectively	57,767	54,739
Accounts receivable other	3,446	5,493
Inventories	77,886	66,416
Deferred income tax	8,188	13,634
Prepaid expenses	11,555	14,665
Other current assets	4,967	5,148
Total current assets	469,619	390,433
Marketable securities, net of current portion	62,237	259,317
Property, plant and equipment, net	176,081	160,863
Capitalized software, net	16,992	13,981
Patents, net	11,758	12,450
Goodwill	140,404	150,308
Purchased intangibles, net	106,619	120,270
License, manufacturing access fees and other assets, net	61,738	60,175
Total assets	$ 1,045,448	$ 1,167,797
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 12,000	$ 14,614
Accrued salaries and employee benefits	28,795	26,825
Other accrued expenses	12,846	13,935
Income tax payable	1,857	634
Short-term borrowings	248,000	240,000
Deferred revenue	1,238	1,166
Total current liabilities	304,736	297,174
Non-current income tax payable	10,019	8,315
Deferred income tax	19,283	29,775
Deferred revenue, net of current portion	3,237	2,500
Other long-term liabilities	7,831	6,654
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized, 45,008,879 and 47,966,156 shares issued and outstanding at December 31, 2011 and December 31, 2010, respectively	5	5
Additional paid-in capital	23,650	195,820

Accumulated other comprehensive income (loss)	(313)	678
Retained earnings	677,000	626,876
Total stockholders equity	700,342	823,379
Total liabilities and stockholders equity	$ 1,045,448	$ 1,167,797

See accompanying notes to consolidated financial statements

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Years Ended December 31,		
	2011	2010	2009
Revenues:			
Product sales	$ 562,588	$ 522,709	$ 483,759
Collaborative research revenue	7,682	14,518	7,911
Royalty and license revenue	5,964	6,100	6,632
Total revenues	576,234	543,327	498,302
Operating expenses:			
Cost of product sales (excluding acquisition-related intangible amortization)	173,645	169,222	152,393
Acquisition-related intangible amortization	11,061	8,847	4,144
Research and development	112,742	111,103	105,970
Marketing and sales	68,396	59,492	53,853
General and administrative	71,394	56,818	61,828
Goodwill and asset impairment charges	12,746		
Total operating expenses	449,984	405,482	378,188
Income from operations	126,250	137,845	120,114
Other income (expense):			
Investment and interest income	8,695	11,765	21,603
Interest expense	(2,070)	(2,216)	(1,857)
Gain on contingent consideration		7,994	
Other-than-temporary impairment loss on equity investment	(39,482)		
Other income (expense), net	(236)	(177)	(58)
Total other income (expense), net	(33,093)	17,366	19,688
Income before income tax	93,157	155,211	139,802
Income tax expense	43,033	48,274	48,019
Net income	$ 50,124	$ 106,937	$ 91,783
Net income per share:			
Basic	$ 1.06	$ 2.20	$ 1.82
Diluted	$ 1.04	$ 2.18	$ 1.79
Weighted average shares outstanding:			
Basic	47,254	48,560	50,356
Diluted	48,387	49,033	50,965

See accompanying notes to consolidated financial statements

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		
	2011	2010	2009
Operating activities			
Net income	$ 50,124	$ 106,937	$ 91,783
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	46,569	44,529	40,382
Amortization of premiums on investments, net of accretion of discounts	9,592	9,573	5,868
Stock-based compensation	24,741	24,075	23,420
Excess tax benefit from employee stock-based compensation	(5,080)	(3,692)	(2,005)
Deferred revenue	850	(1,808)	812
Deferred income tax	(4,220)	(3,745)	(5,786)
Other-than-temporary impairment loss on equity investment	39,482		
Goodwill and asset impairment charges	12,746		
Gain on contingent consideration		(7,994)	
Gain on sale of food safety business			(291)
Loss on disposal of property and equipment	364	1,065	221
Changes in assets and liabilities:			
Trade and other accounts receivable	(1,112)	2,649	(11,303)
Inventories	(11,168)	(1,154)	2,315
Prepaid expenses	408	3,055	1,218
Other current assets	384	(360)	1,912
Other long-term assets	7,164	(559)	(4,123)
Accounts payable	(2,698)	(6,265)	3,500
Accrued salaries and employee benefits	2,981	(133)	(676)
Other accrued expenses	(1,398)	(4,417)	(806)
Income tax payable	10,313	7,688	(2,371)
Other long-term liabilities	1,211	122	961
Net cash provided by operating activities	181,253	169,566	145,031
Investing activities			
Proceeds from sales and maturities of marketable securities	489,241	427,821	438,601
Purchases of marketable securities	(395,190)	(401,434)	(419,019)
Purchases of property, plant and equipment	(41,664)	(30,716)	(32,364)
Purchases of capitalized software	(6,053)	(3,891)	(1,290)
Purchases of intangible assets, including licenses and manufacturing access fees	(5,259)	(2,513)	(7,341)
Net cash paid for business combinations		(53,000)	(183,725)
Proceeds from sale of food safety business			6,357
Cash paid for investment in Roka Bioscience	(3,980)		
Cash paid for investment in Pacific Biosciences		(50,000)	
Other	(209)	(738)	403
Net cash provided by (used in) investing activities	36,886	(114,471)	(198,378)
Financing activities			
Repurchase and retirement of common stock	(250,000)	(99,935)	(174,847)
Proceeds from issuance of common stock and employee stock purchase plan	49,932	31,830	10,923
Payment of contingent consideration		(10,000)	
Repurchase and retirement of restricted stock for payment of taxes	(1,615)	(1,257)	(1,716)
Excess tax benefit from employee stock-based compensation	5,080	3,692	2,005
Borrowings, net	8,000	(228)	238,450
Net cash (used in) provided by financing activities	(188,603)	(75,898)	74,815

Effect of exchange rate changes on cash and cash equivalents	(2,205)	(2,123)	1,026
Net increase (decrease) in cash and cash equivalents	27,331	(22,926)	22,494
Cash and cash equivalents at the beginning of period	59,690	82,616	60,122
Cash and cash equivalents at the end of period	$ 87,021	$ 59,690	$ 82,616
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 2,104	$ 2,358	$ 1,804
Cash paid for taxes	$ 38,744	$ 46,565	$ 54,528

See accompanying notes to consolidated financial statements

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income/(Loss)	Retained Earnings	Total Stockholders Equity
	Shares	Amount				
Balance as of December 31, 2008	52,921	$ 5	$ 382,544	$ 3,055	$ 428,156	$ 813,760
Common stock issued from exercise of stock options	374		6,828			6,828
Repurchase and retirement of common stock	(4,283)		(174,847)			(174,847)
Purchase of common stock through employee stock purchase plan	112		4,095			4,095
Issuance of common stock to board members	4		176			176
Issuance of restricted stock awards, net of cancellations	24					
Issuance of deferred issuance restricted stock awards	34					
Repurchase and retirement of restricted stock for payment of taxes	(42)		(1,716)			(1,716)
Stock-based compensation charges			23,530			23,530
Stock-based compensation income tax benefits			2,005			2,005
Comprehensive income:						
Net income					91,783	91,783
Foreign currency translation adjustment				2,705		2,705
Change in net unrealized loss on marketable securities, net of income tax benefits of $616				(7,981)		(7,981)
Reclassification of net realized gain on marketable securities, net of income tax expense of $3,681				6,837		6,837
Comprehensive income						93,344
Balance as of December 31, 2009	49,144	$ 5	$ 242,615	$ 4,616	$ 519,939	$ 767,175
Common stock issued from exercise of stock options	904		27,438			27,438
Repurchase and retirement of common stock	(2,165)		(99,935)			(99,935)
Purchase of common stock through employee stock purchase plan	117		4,392			4,392
Issuance of common stock to board members	6		282			282
Cancellations of restricted stock awards	(13)					
Repurchase and retirement of restricted stock for payment of taxes	(27)		(1,257)			(1,257)
Stock-based compensation charges			23,398			23,398
Stock-based compensation income tax benefits			(1,113)			(1,113)
Comprehensive income:						
Net income					106,937	106,937
Foreign currency translation adjustment				(1,665)		(1,665)
Change in net unrealized loss on marketable securities, net of income tax benefits of $1,186				(6,644)		(6,644)
Reclassification of net realized gain on marketable securities, net of income tax expense of $2,353				4,371		4,371
Comprehensive income						102,999
Balance as of December 31, 2010	47,966	$ 5	$ 195,820	$ 678	$ 626,876	$ 823,379
Common stock issued from exercise of stock options	1,073		44,866			44,866
Repurchase and retirement of common stock	(4,200)		(250,000)			(250,000)
Purchase of common stock through employee stock purchase plan	101		5,065			5,065
Issuance of common stock to board members	6		415			415
Issuance of restricted stock awards, net of cancellations	52					
Issuance of deferred issuance restricted stock awards	37					
Repurchase and retirement of restricted stock for payment of taxes	(26)		(1,615)			(1,615)
Stock-based compensation charges			24,459			24,459
Stock-based compensation income tax benefits			4,640			4,640

Comprehensive income:						
Net income					50,124	50,124
Foreign currency translation adjustment				(521)		(521)
Change in net unrealized loss on marketable securities, net of income tax benefits of $466				(3,985)		(3,985)
Reclassification of net realized gain on marketable securities, net of income tax expense of $1,893				3,515		3,515
Comprehensive income						49,133
Balance as of December 31, 2011	45,009	$ 5	$ 23,650	$ (313)	$ 677,000	$ 700,342

See accompanying notes to consolidated financial statements

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and summary of significant accounting policies

Organization and basis of presentation

Gen-Probe Incorporated (Gen-Probe or the Company) is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility. The Company s molecular diagnostic products are designed to detect diseases more rapidly and/or accurately than older tests, and are among the fastest-growing categories of the *in vitro* diagnostics (IVD) industry.

Certain prior year amounts have been reclassified to conform to the current year presentation. Such reclassifications did not affect total revenues, income from operations or net income.

Principles of consolidation

These consolidated financial statements include the accounts of Gen-Probe as well as its wholly owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. The Company has not identified any interests in variable interest entities that require consolidation.

In December 2010, the Company acquired Genetic Testing Institute, Inc. (GTI Diagnostics), a privately held Wisconsin corporation now known as Gen-Probe GTI Diagnostics, Inc. GTI Diagnostics has broadened and strengthened the Company s transplant diagnostics business, and has also provided the Company with access to new products in the specialty coagulation and transfusion-related blood bank markets. GTI Diagnostics results of operations have been included in the Company s consolidated financial statements beginning in December 2010.

In October 2009, the Company acquired Prodesse, Inc. (Prodesse), a privately held Wisconsin corporation now known as Gen-Probe Prodesse, Inc. Prodesse develops molecular diagnostic products for a variety of infectious disease applications. Prodesse s results of operations have been included in the Company s consolidated financial statements beginning in October 2009.

In April 2009, the Company acquired Tepnel Life Sciences plc (Tepnel), a United Kingdom (UK) based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd. Tepnel s results of operations have been included in the Company s consolidated financial statements beginning in April 2009.

Use of estimates

The preparation of financial statements in conformity with United States (U.S.) generally accepted accounting principles (GAAP) requires management to make certain estimates and assumptions that affect the amounts reported in the consolidated financial statements. These estimates include assessing the collectability of accounts receivable, recognition of revenues, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; accrued liabilities; inventories; and goodwill and long-lived assets, including patent costs, capitalized software, purchased intangibles and licenses and manufacturing access fees. Actual results could differ from those estimates.

Foreign currencies

The Company translates the financial statements of its non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates on intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders equity under the caption Accumulated other comprehensive income (loss). These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Segment information

The Company currently operates in one business segment: the development, manufacturing, marketing, sales and support of molecular diagnostic products primarily to diagnose human diseases, screen donated human blood and ensure transplant compatibility. Although the Company s products comprise distinct product lines to serve different end markets within molecular diagnostics, the Company does not operate its business in operating segments. The Company is managed by a single functionally-based management team that manages all aspects of the Company s business and reports directly to the Chief Executive Officer. For all periods presented, the Company operated in a single business segment. Product sales by product line and geographic location are presented in Note 16 of these Notes to Consolidated Financial Statements.

Revenue recognition

The Company records shipments of its clinical diagnostic products as product sales when the product is shipped, title and risk of loss have passed to the customer, the consideration is fixed and determinable, and collection of the resulting receivable is reasonably assured.

The Company manufactures blood screening products according to demand schedules provided by its collaboration partner, Novartis Vaccines and Diagnostics, Inc. (Novartis). Upon shipment to Novartis, the Company recognizes blood screening product sales at an agreed upon transfer price and records the related cost of products sold. Based on the terms of the Company s collaboration agreement with Novartis, the Company s ultimate share of the net revenue from sales to the end user is not known until reported to the Company by Novartis. The Company then adjusts blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting the Company s ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized.

In most cases, the Company provides its instrumentation to its clinical diagnostics customers without requiring them to purchase the equipment or enter into an equipment lease. Instead, the Company recovers the cost of providing the instrumentation in the amount it charges for its diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

The Company sells its instruments to Novartis for use in blood screening and records these instrument sales upon delivery since Novartis is responsible for the placement, maintenance and repair of the units with its customers. The Company also sells instruments to its clinical diagnostics customers and records sales of these instruments upon delivery and customer acceptance. For certain customers with non-standard payment terms, instrument sales are recorded based upon expected cash collection. Prior to delivery, each instrument is tested to meet Gen-Probe s specifications and the specifications of the United States Food and Drug Administration (FDA), and is shipped fully assembled. Customer acceptance of the Company s clinical diagnostic instrument systems requires installation and training by the Company s technical service personnel. Installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company records revenue on its research products and services in the period during which the related costs are incurred or the services are provided. This revenue consists of outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

Revenue arrangements with multiple deliverables are evaluated for proper accounting treatment. In these arrangements, the Company records revenue as separate units of accounting if the delivered items have value to the customer on a stand-alone basis, if the arrangement includes a general right of return relative to the delivered items, and if delivery or performance of the undelivered items is considered probable and substantially within the Company s control. For transactions entered into prior to 2011, consideration was allocated to each unit of accounting based on its relative fair value when objective and reliable evidence of fair value existed for all units of accounting in an arrangement. The fair value of an item was the price charged for the product, if the item was sold on a stand-alone basis. When the Company was unable to establish fair value for delivered items or when fair value of undelivered items had not been established, revenue was deferred until all elements were delivered and services had been performed or until fair value could be objectively determined for any undelivered elements. Beginning in 2011, arrangement consideration is allocated at the inception of the arrangement to all deliverables using the relative selling price method that is based on a three-tier hierarchy. The relative selling price method requires that the estimated selling price for each deliverable be based on vendor-specific objective evidence (VSOE) of fair value, which represents the price charged for each deliverable when it is sold separately or, for a deliverable not yet being sold separately, the price established by management. When VSOE of fair value is not available, third-party evidence (TPE) of fair value is acceptable, or a best estimate of selling price if neither VSOE nor TPE are available. A best estimate of selling price should be consistent with the objective of determining the price at which the Company would transact if the deliverable were sold regularly on a stand-alone basis and should also take into account market conditions and company-specific factors.

The Company recognizes collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the applicable contracts. Non-refundable license fees with stand-alone value are recognized at the time that the Company has satisfied all performance obligations. License fees without stand-alone value are recognized in combination with any undelivered performance obligations. Milestone consideration that is contingent upon achievement of a milestone in its entirety is recorded as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. These criteria include: (i) the consideration being earned should be commensurate with either the Company s performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company s performance to achieve the milestone; (ii) the consideration being earned should relate solely to past performance; (iii) the consideration being earned should be reasonable relative to all deliverables and payment terms in the arrangement; and (iv) the milestone should be considered in its entirety and cannot be bifurcated into substantive and non-substantive components. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue on the Company s consolidated balance sheets.

Royalty and license revenue is recognized related to the sale or use of the Company s products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and adjusts for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenue upon receipt of royalty statements from the applicable licensee.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cost of product sales

Cost of product sales reflects the costs applicable to products shipped for which product sales revenue is recognized in accordance with the Company s revenue recognition policy. The Company manufactures products for commercial sale as well as development stage products for internal use or clinical evaluation. The Company classifies costs for commercial products to Cost of product sales and costs for internal use or clinical evaluations to Research and development costs.

Stock-based compensation

The Company uses the Black-Scholes-Merton option pricing model to value stock options granted. The determination of the fair value of stock option awards on the date of grant using the Black-Scholes-Merton model is affected by the Company s stock price and the implied volatility on its traded options, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and the Company s expected stock price volatility over the term of the awards.

Stock-based compensation expense is recognized for restricted stock, deferred issuance restricted stock, performance stock awards, which include awards subject to performance conditions and/or market conditions, stock options, and shares purchasable under the Company s Employee Stock Purchase Plan (ESPP). Stock-based compensation expense for restricted stock, deferred issuance restricted stock, and performance condition stock awards is measured based on the closing fair market value of the Company s common stock on the date of grant. Stock-based compensation expense for market condition stock awards is measured based on the fair value of the award on the date of grant using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple point variables that determine the probability of satisfying the market condition stipulated in the grant and calculates the fair value of the award. Certain of these costs are capitalized into inventory on the Company s consolidated balance sheets, and are recognized as an expense when the related products are sold.

Research and development

Research and development expenses consist of costs incurred for internal and collaborative research and development. Expenditures relating to research and development are expensed in the period incurred.

The Company does not separately track all of the costs applicable to collaborative research revenue, as the Company does not distinguish between the Company s internal development activities and the development efforts made pursuant to agreements with third parties. The costs associated with collaborative research revenue are based on fully burdened full time equivalent rates and are reflected in the Company s consolidated statements of income under the captions Research and development, Marketing and sales, and General and administrative, based on the nature of the costs.

Advertising costs

Advertising costs are expensed as incurred and are recorded within marketing and sales expenses. Advertising costs were $1.2 million, $0.6 million, and $0.8 million for the years ended December 31, 2011, 2010 and 2009, respectively.

Shipping and handling expenses

Shipping and handling expenses included in cost of product sales totaled approximately $10.5 million, $7.9 million, and $7.3 million for the years ended December 31, 2011, 2010 and 2009, respectively.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Contingencies

Contingent gains are not recorded in the Company s consolidated financial statements since this accounting treatment could result in the recognition of gains that might never be realized. Contingent losses are only recorded in the Company s consolidated financial statements if it is probable that a loss will result from a contingency and the amount can be reasonably estimated.

Income tax

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. The impact of tax law and rate changes is reflected in income in the period such changes are enacted. As needed, the Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized based on expected future taxable income.

The Company s income tax returns are based on calculations and assumptions that are subject to examination by various tax authorities. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of these examinations and any future examinations in determining the adequacy of its provision for income taxes. As part of its assessment of potential adjustments to its tax returns, the Company increases its tax liabilities or decreases its deferred tax assets to the extent a tax position taken on the Company s return is not more likely than not to be sustained based upon its technical merits. The Company reviews, at least quarterly, the likelihood and amount of potential adjustments and adjusts the income tax provision, the current tax liability and deferred taxes in the period in which credible new information causes the Company to change its assessment of the likelihood of a tax position being sustained.

Net income per share

Diluted net income per share is reported based on the more dilutive of the treasury stock or the two-class method. Under the two-class method, net income is allocated to common stock and participating securities. The Company s restricted stock, deferred issuance restricted stock and performance stock awards meet the definition of participating securities. Basic net income per share under the two-class method is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share under the two-class method is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share when the combined exercise price, unrecognized stock-based compensation and assumed tax benefits upon exercise are greater than the average market price for the Company s common stock because their effect is anti-dilutive. Potentially dilutive securities totaling approximately 1.0 million, 3.8 million and 3.9 million for the years ended December 31, 2011, 2010 and 2009, respectively, were excluded from the calculations of diluted earnings per share (EPS) below because of their anti-dilutive effect.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table sets forth the computation of basic and diluted EPS for the years ended December 31, 2011, 2010 and 2009 (in thousands, except per share amounts):

	Years Ended December 31,		
	2011	2010	2009
Basic Net Income per Share			
Net income	$ 50,124	$ 106,937	$ 91,783
Less: income allocated to participating securities	(60)	(273)	(335)
Net income allocated to common stockholders	$ 50,064	$ 106,664	$ 91,448
Weighted average common shares outstanding basic	47,254	48,560	50,356
Net income per share basic	$ 1.06	$ 2.20	$ 1.82
Diluted Net Income per Share			
Net income	$ 50,124	$ 106,937	$ 91,783
Less: income allocated to participating securities	(59)	(270)	(331)
Net income allocated to common stockholders	$ 50,065	$ 106,667	$ 91,452
Weighted average common shares outstanding basic	47,254	48,560	50,356
Dilutive securities	1,133	473	609
Weighted average common shares outstanding diluted	48,387	49,033	50,965
Net income per share diluted	$ 1.04	$ 2.18	$ 1.79

Cash and cash equivalents

Cash and cash equivalents consist primarily of highly liquid cash investment funds with original maturities of three months or less when acquired.

Fair value measurements

For details on the assets and liabilities subject to fair value measurements and the related valuation techniques used, refer to Note 8 of these Notes to Consolidated Financial Statements.

The Company accounts for assets and liabilities at fair value in accordance with Accounting Standards Codification (ASC) Topic 820, Fair Value Measurements and Disclosures (ASC Topic 820). ASC Topic 820 defines fair value and establishes a framework for measuring fair value based on a three tiered valuation approach. The Company periodically reviews and evaluates the application of these valuation techniques to its assets and liabilities.

Marketable securities

The Company s marketable securities include equity securities, mutual funds, treasury securities, tax advantaged municipal securities and Federal Deposit Insurance Corporation (FDIC) insured corporate bonds. The primary objectives of the Company s marketable debt security investment portfolio are liquidity and safety of principal. Investments are made with the goal of achieving the highest rate of return consistent with these two objectives. The Company s investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. The equity securities consist of investments in common stock.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The deferred compensation plan assets are invested in mutual funds with quoted market prices. During the fourth quarter of 2011, the Company converted its deferred compensation plan assets into mutual funds.

All of the Company s marketable securities, except for mutual funds, are classified as available-for-sale securities. Mutual fund investments are classified as trading securities. Marketable debt and equity securities classified as available-for-sale are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity under the caption Accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in Investment and interest income. The Company s mutual funds are carried at fair value, with unrealized gains and losses included in Investment and interest income.

Interest and dividend income, as well as realized gains and losses on marketable securities, are included in Investment and interest income. The cost of securities sold is based on the specific identification method. Declines in value judged to be other-than-temporary on marketable securities are included within the Other income (expense) section of the consolidated statements of income.

The Company periodically reviews its marketable equity securities for other-than-temporary declines in fair value below their cost basis, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. When assessing marketable equity securities for other-than-temporary declines in value, the Company considers factors including: the significance of the decline in value compared to the cost basis; the underlying factors contributing to a decline in the prices of securities in a single asset class; how long the market value of the investment has been less than its cost basis; any market conditions that impact liquidity; the views of external investment analysts; the financial condition and near-term prospects of the investee; any news or financial information that has been released specific to the investee; and the outlook for the overall industry in which the investee operates.

The contractual terms of the debt securities held by the Company do not permit the issuer to settle the securities at a price less than the amortized cost of the investments. The Company does not consider its investments in marketable debt securities with a current unrealized loss position to be other-than-temporarily impaired at December 31, 2011 and 2010 because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at December 31, 2011 and 2010 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of current portion, reflecting the Company s current intent and ability to hold such investments to maturity.

Accounts receivable

Accounts receivable are recorded at the invoiced amount and are non-interest bearing. The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. Credit losses historically have been minimal and within management s expectations. If the financial condition of the Company s customers were to deteriorate, resulting in an impairment of the customers ability to make payments, additional allowances would be required.

Concentration of credit risk

The Company sells its diagnostic products primarily to established large reference laboratories, public health institutions and hospitals. Credit is extended based on an evaluation of the customer s financial condition and generally collateral is not required.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and marketable debt securities. The Company limits its exposure to credit loss by placing its cash with high credit quality financial institutions. The Company generally invests its excess cash in investment grade municipal securities. The Company s marketable securities are presented in Note 7 of these Notes to Consolidated Financial Statements.

Inventories

Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out method. A reserve is recorded for excess and obsolete inventory based on management s review of inventories on hand, compared to estimated future usage and sales, shelf-life and assumptions about the likelihood of obsolescence.

Property, plant and equipment

Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment is provided using the straight-line method over the estimated useful lives of the assets as follows:

	Years
Building	10-50
Machinery and equipment	3-8
Furniture and fixtures	3

Depreciation expense was $25.6 million, $26.8 million, and $27.6 million for the years ended December 31, 2011, 2010 and 2009, respectively. Amortization of building improvements is provided over the shorter of the remaining life of the lease or the estimated useful life of the asset.

Asset retirement obligations

Obligations recorded are associated with the retirement of tangible long-lived assets related to leased facilities and the associated asset retirement costs. The Company records the fair value of a liability for an asset retirement obligation in the period in which it is incurred if a reasonable estimate of fair value can be made. In addition, the asset retirement cost is capitalized as part of the asset s carrying value and subsequently expensed over the asset s useful life. The Company s consolidated balance sheets at December 31, 2011 and 2010 included asset retirement obligations of $1.1 million and $0.5 million, respectively.

Patent costs

The Company capitalizes the costs incurred to file and prosecute patent applications. The Company amortizes these costs on a straight-line basis over the lesser of the remaining useful life of the related technology or eight years. Capitalized patent costs are included in License, manufacturing access fees and other assets, net on the consolidated balance sheets. All costs related to abandoned patent applications are recorded as General and administrative expenses.

Capitalized software costs

The Company capitalizes costs incurred in the development of computer software related to products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the shorter of the estimated life of the related product or ten years.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Goodwill and intangible assets

The Company capitalizes license fee payments that relate to approved products and acquired intangibles with alternative future uses.

The Company capitalizes manufacturing access fees that it pays when (i) the fee embodies a probable future benefit that involves a capacity, singly or in combination with other assets, to contribute directly or indirectly to future net cash inflows, (ii) the Company can obtain the benefit and control others access to it, and (iii) the transaction or other event giving rise to the entity s right to or control of the benefit has already occurred.

Intangible assets that the Company acquires are initially recognized and measured based on their fair value. The Company uses the present value technique of estimated future cash flows to measure the fair value of assets at the date of acquisition. Those cash flow estimates incorporate assumptions based on historical experience with selling similar products in the marketplace. The useful life of an intangible asset to an entity is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of that entity. The Company amortizes its capitalized intangible assets over the remaining economic life of the relevant technology using the straight-line method, which currently ranges from 2 to 20 years, as the cash flows generated by these intangible assets cannot be reliably determined.

The Company s business acquisitions typically result in the recording of goodwill and other intangible assets, and the recorded values of those assets may become impaired in the future. The Company also acquires intangible assets in other types of transactions. As of December 31, 2011, the Company s goodwill and intangible assets (excluding capitalized software), net of accumulated amortization, were $140.4 million and $156.3 million, respectively. Of the $140.4 million of goodwill recorded at December 31, 2011, $62.0 million, $33.0 million, and $26.8 million related to the acquisitions of Tepnel, Prodesse and GTI Diagnostics, respectively.

The valuation of intangible assets requires management to make estimates and assumptions that affect the Company s consolidated financial statements. For intangible assets purchased in a business combination, the estimated fair values of the assets acquired are used to establish their recorded values. Valuation techniques consistent with the market approach, income approach and/or cost approach are used to measure fair value. An estimate of fair value can be affected by many assumptions which require significant judgment. For example, the income approach requires assumptions related to the appropriate business model to be used to estimate cash flows, total addressable market, pricing and share forecasts, competition, technology obsolescence, future tax rates and discount rates. The Company s estimates of the fair value of certain assets, or its conclusion that the value of certain assets is not reliably estimable, may differ materially from determinations made by others who use different assumptions or utilize different valuation models. New information may arise in the future that affects the Company s fair value estimates and could result in adjustments to its estimates in the future, which could have an adverse impact on its results of operations.

The Company assesses the impairment of goodwill and intangible assets whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Impairment is reviewed at least annually at the reporting unit level, and occurs at the same time in the fourth quarter of each year, unless circumstances indicate that impairment has occurred before the fourth quarter of any given year. The Company utilizes a discounted cash flow analysis to estimate the fair value of each reporting unit. The evaluation includes management estimates of cash flow projections based on an internal strategic review. Key assumptions from this strategic review include revenue growth, gross and operating margin growth, and the Company s weighted average cost of capital. The Company uses specific discount rates to determine the estimated value of each reporting unit. The Company may supplement its discounted cash flow analysis with other acceptable valuation

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

techniques, when deemed necessary. If actual results are not consistent with the Company s estimates and assumptions used in estimating future cash flows and asset fair values, the Company may be exposed to losses that could be material.

Factors the Company considers important that could trigger impairment include the following:

- significant under performance relative to historical or projected future operating results;
- significant changes in the manner of the Company s use of the acquired assets or the strategy for its overall business;
- significant negative industry or economic trends;
- significant declines in the Company s stock price for a sustained period; and
- decreased market capitalization relative to net book value.

When there is an indication that the carrying value of goodwill or an intangible asset may not be recoverable based upon the existence of one or more of the above indicators or other factors, an impairment loss is recognized if the carrying amount exceeds its fair value. Any resulting impairment loss could have an adverse impact on the Company s operating expenses.

In the fourth quarter of 2011, the Company recorded impairment charges related to goodwill and intangible assets acquired in business combinations. See Note 2 of these Notes to Consolidated Financial Statements for further details.

Self-insurance reserves

The Company s consolidated balance sheets as of December 31, 2011 and 2010 include approximately $2.6 million and $1.3 million, respectively, of liabilities associated with employee medical costs that are retained by the Company. The Company estimates the liability for such claims on an undiscounted basis based upon various assumptions which include, but are not limited to, the Company s historical loss experience and projected loss development factors. The estimated liability is also subject to adjustment in the future based upon changes in claims experience, including changes in the number of incidents (frequency) and change in the ultimate cost per incident (severity).

Accumulated other comprehensive income (loss)

All components of comprehensive income, including net income, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income (loss), which includes certain changes in stockholders equity, such as foreign currency translation of the Company s wholly owned subsidiaries financial statements and unrealized gains and losses on its available-for-sale securities, are reported, net of their related tax effect, to arrive at comprehensive income.

Pending adoption of recent accounting pronouncements

Accounting Standards Update 2011-04

In May 2011, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) on fair value measurement. The ASU expands the disclosure requirements of ASC Topic 820 for fair

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

value measurements and makes other amendments. Specifically, the ASU clarifies the accounting guidance for highest-and-best-use and valuation-premise concepts for non-financial assets, application to financial assets and financial liabilities with offsetting positions in market risks or counterparty credit risk, premiums or discounts in fair value measurement, and fair value of an instrument classified in an entity s stockholders equity. Additionally, the ASU expands the disclosure requirements under ASC Topic 820, particularly for Level 3 inputs. The ASU is effective for interim and annual reporting periods of the Company beginning January 1, 2012. Early adoption is not permitted. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

Accounting Standards Update 2011-05 and 2011-12

In June 2011, the FASB issued ASU 2011-05 on the presentation of comprehensive income. The ASU removes the presentation options in ASC Topic 220, Comprehensive Income, and requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. The ASU does not change the items that must be reported in other comprehensive income (loss) and does not require any incremental disclosures in addition to those already required under existing accounting guidance. The ASU is effective for interim and annual reporting periods of the Company beginning January 1, 2012. The guidance must be applied retrospectively for all periods presented in the financial statements. Early adoption is permitted. The Company intends to adopt this guidance beginning January 1, 2012. The adoption of this guidance will not have any effect on the Company s consolidated financial statements.

In December 2011, the FASB issued ASU 2011-12, deferring certain provisions of ASU 2011-05. One of the provisions of ASU 2011-05 required entities to present reclassification adjustments out of accumulated other comprehensive income (loss) by component in both the statement in which net income is presented and the statement in which other comprehensive income (loss) is presented (for both interim and annual financial statements). This requirement is indefinitely deferred by ASU 2011-12 and will be further deliberated by the FASB at a future date. The effective date of ASU 2011-12 is the same as that for the unaffected provisions of ASU 2011-05.

Accounting Standards Update 2011-08

In September 2011, the FASB issued ASU 2011-08 on performing goodwill impairment testing. The ASU amends the guidance in ASC Topic 350-20, Goodwill. Under the revised guidance, entities testing goodwill for impairment have the option of performing a qualitative assessment before calculating the fair value of the reporting unit (step 1 of the goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required. The ASU does not change how goodwill is calculated or assigned to reporting units, does not revise the requirement to test goodwill annually for impairment, and does not amend the requirement to test goodwill for impairment between annual tests if events and circumstances warrant. The ASU provides examples of events and circumstances to consider for qualitative assessment. The amendments are effective for annual and interim goodwill impairment tests performed by the Company beginning January 1, 2012. Early adoption is permitted. The Company plans to adopt this guidance in the first quarter of 2012 for its goodwill impairment testing. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Business combinations

The acquisitions described below were accounted for as business combinations and, accordingly, the Company has included the results of operations of the acquired entities in its consolidated statements of income from the respective date of acquisition. Neither separate financial statements nor pro forma results of operations have been presented for any of these acquisitions because the acquisitions did not meet the quantitative materiality tests under Regulation S-X.

Acquisition of GTI Diagnostics

In December 2010, the Company acquired GTI Diagnostics, a privately held specialty diagnostics company focused on the transplantation, specialty coagulation and transfusion-related blood bank markets, for $53.0 million on a net-cash basis. As a result of the acquisition, GTI Diagnostics became a wholly owned subsidiary of the Company. The Company financed the acquisition with cash on hand.

The Company finalized the purchase price allocation in the fourth quarter of 2011. The $53.0 million purchase price for GTI Diagnostics exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company originally allocated $28.0 million to goodwill. During the year ended December 31, 2011, the Company recorded adjustments to the purchase price allocation resulting in a net decrease of $1.2 million to goodwill. The final purchase price allocation for the Company s acquisition of GTI Diagnostics is as follows (in thousands):

Total purchase price	$ 53,000
Net working capital	$ 7,882
Fixed assets	922
Goodwill	26,801
Deferred tax liabilities	(10,862)
Other intangible assets	32,100
Liabilities assumed	(3,843)
Allocated purchase price	$ 53,000

The fair values of the acquired identifiable intangible assets with definite lives included in the final purchase price allocation are as follows (in thousands):

Patents	$ 10,600
In-process research and development	11,900
Customer relationships	3,500
Trade secrets	6,100
Total	$ 32,100

The amortization periods for the acquired identifiable intangible assets with definite lives are as follows: six to nine years for patents, ten years for customer relationships, 20 years for trade secrets, and an estimated life to be determined for each in-process research and development project (to commence upon commercialization of the associated product). The Company is amortizing the acquired identifiable intangible assets set forth in the table above using the straight-line method of amortization. The Company believes that the use of the straight-line method is appropriate given the high customer retention rate of the acquired business, the historical and projected growth of revenues and related cash

flows, and because the timing and amount of cash flows generated by these

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assets cannot be reliably determined. The Company will monitor and assess the acquired identifiable intangible assets and will adjust, if necessary, the expected life, amortization method or carrying value of such assets to best match the underlying economic value.

In the fourth quarter of 2011, the Company evaluated the value assigned to the acquired in-process research and development assets obtained in connection with the Company s acquisition of GTI Diagnostics in December 2010. The Company determined, based on a lower level of probable sales than was estimated at the time of the business combination, that the fair value of certain acquired in-process research and development assets had fallen below the $11.9 million recorded at the time of acquisition. The current fair value for the in-process research and development assets has been determined by using the excess earnings method. An impairment charge of $4.0 million is included in Goodwill and asset impairment charges on the accompanying Consolidated Statements of Income, which reduces the value of the in-process research and development assets to a revised fair value of $7.9 million as of December 31, 2011.

The estimated amortization expense for the acquired identifiable intangible assets over future periods, excluding the in-process research and development assets due to uncertainty with respect to the commercialization of such assets, is as follows (in thousands):

Years Ending December 31,	
2012	$ 1,981
2013	1,981
2014	1,981
2015	1,981
2016	1,981
Thereafter	8,300
Total	$ 18,205

Acquisition of Prodesse, Inc.

In October 2009, the Company acquired Prodesse, a privately held Wisconsin corporation, for approximately $60.0 million, subject to a designated pre-closing operating income adjustment, and up to an aggregate of $25.0 million in potential additional cash payments based on the achievement of certain specified performance measures. In July 2010, the Company received FDA clearance of its ProFAST+ assay, thereby satisfying one of the acquisition-related milestones and triggering a $10.0 million payment to former Prodesse securityholders. No other milestones were satisfied and there is no contingent consideration liability remaining as of December 31, 2011. Further information regarding the contingent consideration can be found in Note 8 of these Notes to Consolidated Financial Statements. As a result of the acquisition, Prodesse (which is now known as Gen-Probe Prodesse, Inc.) became a wholly owned subsidiary of the Company. The Company financed the acquisition through existing cash on hand.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The final allocation of the purchase price for the acquisition of Prodesse is as follows (in thousands):

Total purchase price	$ 62,005
Net working capital	$ 10,240
Fixed assets	644
Goodwill	32,981
Deferred tax liabilities	(21,369)
Other intangible assets	58,570
Liabilities assumed	(1,067)
Contingent consideration	(17,994)
Allocated purchase price	$ 62,005

The fair values of the acquired identifiable intangible assets with definite lives are as follows (in thousands):

In-process research and development	$ 1,070
Developed technology	24,500
Customer relationships	31,800
Trademarks / trade names	1,200
Total	$ 58,570

The amortization periods for the acquired identifiable intangible assets with definite lives are as follows: five years for in-process research and development, 12 years for developed technology, 12 years for customer relationships, and 20 years for trademarks and trade names. The Company is amortizing the acquired identifiable intangible assets set forth in the table above using the straight-line method of amortization. The Company believes that the use of the straight-line method is appropriate given the high customer retention rate of the acquired business, the historical and projected growth of revenues and related cash flows, and because the timing and amount of cash flows generated by these assets cannot be reliably determined. The Company will monitor and assess the acquired identifiable intangible assets and will adjust, if necessary, the expected life, amortization method or carrying value of such assets to best match the underlying economic value.

In addition to acquiring Prodesse s existing products, the Company also acquired other products that can be classified as next generation products, which were in the process of being developed. Overall, a value of approximately $1.1 million was capitalized and classified as in-process research and development for the products under development. In December 2010, ProAdeno+, the product included within the in-process research and development intangible asset, was approved by the FDA for commercial use and the Company began selling the product. The Company commenced amortizing the in-process research and development intangible asset in December 2010 upon FDA approval.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The estimated amortization expense for the acquired identifiable intangible assets over future periods is as follows (in thousands):

Years Ending December 31,	
2012	$ 4,966
2013	4,966
2014	4,966
2015	4,948
2016	4,752
Thereafter	23,445
Total	$ 48,043

Acquisition of Tepnel Life Sciences plc

In April 2009, the Company acquired Tepnel, a UK-based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd., which has two principal businesses, molecular diagnostics and research products and services. As a result of the acquisition, Tepnel became a wholly-owned subsidiary of the Company.

Upon consummation of the acquisition, each issued ordinary share of Tepnel was cancelled and converted into the right to receive 27.1 pence in cash, or approximately $0.40 based on the then applicable Great Britain Pound (GBP) to United States Dollar (USD) exchange rate. In connection with the acquisition, the holders of issued and outstanding Tepnel capital stock, options and warrants received total net cash of approximately £92.8 million, or approximately $137.1 million based on the then applicable GBP to USD exchange rate. The acquisition was financed through amounts borrowed by the Company under a senior secured revolving credit facility established between the Company and Bank of America, N.A.

The final allocation of the purchase price for the acquisition of Tepnel is as follows (in thousands):

Total purchase price	$ 137,093
Exchange rate differences [(1)]	(568)
Allocated purchase price	$ 136,525
Net working capital	$ 14,811
Fixed assets	11,352
Goodwill	70,395
Deferred tax liabilities	(14,148)
Other intangible assets	57,497
Liabilities assumed	(3,382)
Allocated purchase price	$ 136,525

(1) Difference caused by exchange rate fluctuations between the date of acquisition and the date funds were wired.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The fair values of the acquired identifiable intangible assets with definite lives are as follows (in thousands):

Patents	$ 294
Software	441
Customer relationships	45,439
Trademarks / trade names	11,323
Total	$ 57,497

The amortization periods for the acquired identifiable intangible assets with definite lives are as follows: ten years for patents, five years for software, 12 years for customer relationships, and 20 years for trademarks and trade names. The Company is amortizing the primary acquired identifiable intangible assets, including the customer relationships and trademarks and trade names, using the straight-line method of amortization. The Company believes that the use of the straight-line method is appropriate given the high customer retention rate of the acquired businesses, the historical and projected growth of revenues and related cash flows, and because the timing and amount of cash flows generated by these assets cannot be reliably determined. The Company will monitor and assess the acquired identifiable intangible assets and will adjust, if necessary, the expected life, amortization method or carrying value of such assets to best match the underlying economic value.

In the fourth quarter of 2011, the Company recorded an $8.7 million goodwill impairment charge relating to Tepnel s European operations, which primarily consist of the Company s research products and services business. Due to market weakness affecting contract research organizations, the Company reduced its revenue outlook for its research products and services business. As a result, the Company s 2011 annual step 1 impairment test for goodwill indicated that the carrying value of the European operations unit exceeded its fair value. The fair value calculation was determined using a discounted cash flow analysis, assuming a weighted average cost of capital and long-term growth rate of 10% and 3%, respectively. The acquired identifiable intangible assets with definite lives were also evaluated for impairment but were not considered to be impaired as of December 31, 2011. The goodwill impairment charge has been recorded within Goodwill and asset impairment charges on the Company s Consolidated Statements of Income.

The estimated amortization expense for the acquired identifiable intangible assets over future periods is as follows (in thousands):

Years Ending December 31,	
2012	$ 4,163
2013	4,163
2014	4,097
2015	4,075
2016	4,075
Thereafter	21,586
Total	$ 42,159

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Changes in goodwill resulting from acquisitions

Changes in goodwill for the years ended December 31, 2011 and 2010 were as follows (in thousands):

Goodwill balance as of December 31, 2009	$ 122,680
Additional goodwill recognized	28,005
Changes due to foreign currency translation	(377)
Goodwill balance as of December 31, 2010	150,308
Purchase accounting adjustments to goodwill	(1,203)
Impairment loss on goodwill recognized	(8,752)
Changes due to foreign currency translation	51
Goodwill balance as of December 31, 2011	$ 140,404

Note 3. Consolidation of UK operations

Following its acquisition of Tepnel in April 2009, the Company had four locations in the UK: Manchester, Cardiff, Livingston and Abingdon. In order to accommodate the anticipated growth in the business and to optimize expenses, the Company decided to consolidate its UK operations to Manchester and Livingston. This consolidation was communicated internally in May 2010. Consolidation activities related to the employees and facilities are being accounted for under ASC Topic 420, Exit or Disposal Costs (ASC Topic 420). The Company estimates that expenses related to this consolidation will total approximately $4.5 million and be incurred over a two-year period, as the consolidation will occur in phases. These expenses will include termination costs, including severance costs related to the elimination of certain redundant positions and relocation costs for certain key employees, and site closure costs.

During the years ended December 31, 2011 and 2010, the Company recorded approximately $2.7 million and $1.1 million of termination and site closure costs, respectively. These amounts are included in general and administrative expenses in the Company s consolidated statements of income.

The following table summarizes the restructuring activities accounted for under ASC Topic 420 for the years ended December 31, 2011 and 2010, as well as the remaining restructuring accrual recorded on the Company s consolidated balance sheets as of December 31, 2011 (in thousands):

	Termination Costs	Site Closure Costs	Total
Restructuring reserves as of December 31, 2009	$	$	$
Charged to expenses	496	625	1,121
Amounts paid	(207)	(547)	(754)
Foreign currency translation	(2)		(2)
Restructuring reserves at December 31, 2010	287	78	365
Charged to expenses	805	1,916	2,721
Amounts paid	(834)	(1,529)	(2,363)
Foreign currency translation	9	(25)	(16)

Restructuring reserves at December 31, 2011	$ 267	$ 440	$ 707

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Spin-off of industrial testing assets to Roka Bioscience, Inc.

In September 2009, the Company spun-off its industrial testing assets, including the Closed Unit Dose Assay (CUDA) system, to Roka Bioscience, Inc. (Roka), a newly formed private company focused on developing rapid, highly accurate molecular assays for biopharmaceutical production, water and food safety testing, and other applications. In consideration for the contribution of assets valued at $0.7 million, the Company received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis.

In addition to the CUDA system, the Company contributed to Roka other industrial assets and the right to use certain of its technologies and related know-how in certain industrial markets. These markets include biopharmaceutical production, water and food safety testing, veterinary testing, environmental testing and bioterrorism testing. Roka also has rights to develop certain infection control tests for use on the CUDA system.

The Company will receive royalties on any potential Roka product sales, and retains rights to use the CUDA system for clinical diagnostic applications. In addition, the Company is providing contract manufacturing and certain other services to Roka. In May 2011, the Company entered into a supply agreement with Roka, pursuant to which Roka has the right to purchase PANTHER instruments from the Company for use in certain industrial markets.

During 2011, the Company invested an additional $4.0 million in Roka, bringing its total investment in Roka to $4.7 million. As of December 31, 2011, the Company owned approximately 14.7% of Roka s capital stock calculated on a fully diluted basis. The Company considers Roka to be a variable interest entity in accordance with ASC Topic 810, Consolidation. However, the Company is not the primary beneficiary of Roka and therefore has not consolidated Roka s financial position or results of operations in the Company s consolidated financial statements.

Note 5. Stock-based compensation

The following table presents the weighted average assumptions used by the Company to estimate the fair value of stock options and performance stock awards granted under the Company s equity incentive plans and the shares purchasable under the ESPP, as well as the resulting average fair values:

	Years Ended December 31,		
	2011	2010	2009
Stock options			
Risk-free interest rate	1.6%	2.0%	2.0%
Volatility	31.1%	32.0%	35.0%
Dividend yield			
Expected term (years)	4.3	4.4	4.3
Resulting average fair value	$ 17.95	$ 12.85	$ 12.64
Performance stock awards[1]			
Risk-free interest rate	1.3%		
Volatility	33.4%		
Dividend yield			
Expected term (years)	2.9		
Resulting average fair value	$ 82.58	$	$
ESPP			
Risk-free interest rate	0.1%	0.2%	0.8%
Volatility	28.2%	24.0%	43.0%
Dividend yield			
Expected term (years)	0.5	0.5	0.5

Resulting average fair value	$ 14.83	$ 9.64	$ 11.66

(1) These assumptions apply to the Company s market condition stock awards granted in February 2011. Performance condition stock awards granted in February 2010 were valued at $42.66 per share based on the closing fair market value of the Company s common stock on the date of grant.

Table of Contents

GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The risk-free interest rate assumption is based upon observed interest rates appropriate for the terms of the Company s employee stock options and shares purchasable under the ESPP. The Company uses a blend of historical and implied volatility for the expected volatility assumption. The selection of a blend of historical and implied volatility data to estimate expected volatility was based upon the availability of actively traded options on the Company s stock and the Company s assessment that this method of estimating volatility is more representative of future stock price trends than using either historical or implied data individually. The Company has not historically made dividend payments, but is required to assume a dividend yield as an input to the Black-Scholes-Merton model. The dividend yield is based on the Company s expectation that no dividends will be paid in the foreseeable future. The expected term of employee stock options represents the weighted-average period the stock options are expected to remain outstanding. The Company uses a midpoint scenario method, which assumes that all vested, outstanding options are settled halfway between the date of measurement and their expiration date. The calculation also leverages the history of actual exercises and post-vesting cancellations. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company assesses the forfeiture rate on an annual basis and revises the rate when deemed necessary. The Company assesses the probability of achievement of the performance conditions under performance stock awards on a quarterly basis.

The Company s unrecognized stock-based compensation expense, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards was approximately as follows (in thousands, except number of years):

Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of December 31, 2011
Options	2.5	$ 25,476
Employee stock purchase plan	0.2	112
Performance stock awards	2.0	3,840
Restricted stock	1.7	2,393
Deferred issuance restricted stock	1.4	302
Total		$ 32,123

The following table summarizes the stock-based compensation expense that the Company recorded in its consolidated statements of income (in thousands):