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 cover