GEN PROBE INC
Form 10-K
February 23, 2012
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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.

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For the Year Ended December 31, 2011

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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.

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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.

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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.

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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.

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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

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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

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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.

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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.

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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.

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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).

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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.

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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.

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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.

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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