GEN PROBE INC
Form 10-K
February 25, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934.

(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, 2009

or

o **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: 001-31279

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 o

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 o 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 o

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 o No o

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. o

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 o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

As of June 30, 2009, 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 $2.2 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, 2010, 49,451,207 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.

GEN-PROBE INCORPORATED

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PART I

TRADEMARKS AND TRADE NAMES

ACCUPROBE, AMPLIFIED MTD, APTIMA, APTIMA COMBO 2, DTS, GASDIRECT, GEN-PROBE, LEADER, LIFECODES, PACE, PANTHER, PRODESSE, 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., or Novartis. XMAP is a trademark of Luminex Corporation, or Luminex. AVODART is a trademark of GlaxoSmithKline. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Use or display by us of other parties trademarks, trade dress or products in this Annual Report does not imply a relationship with, or endorsement or sponsorship of, us by 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 believes, expects, hopes, may, will, plans, intends, estimates, could, should, would, continue, seeks or anticipates, or otl (including their use in the negative), or by discussions of future matters, such as the development of new products, technology enhancements, 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. 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 nucleic acid tests, or NATs, used primarily to diagnose human diseases and screen donated human blood. NATs 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 products 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.

In 2009, we expanded our portfolio of products with acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel Life Sciences plc, or Tepnel, offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse, Inc., or Prodesse, added a portfolio of real-time polymerase chain reaction, or real-time PCR, products for detecting influenza and other infectious organisms.

In blood screening, we developed and manufacture the PROCLEIX 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. Our blood screening products are marketed worldwide by Novartis.

Several of our current and future molecular tests can be performed on our TIGRIS instrument, the only fully automated, high-throughput NAT system for diagnostics and blood screening. We are building on the success of our TIGRIS instrument system by developing our next-generation PANTHER instrument, which is designed to be a versatile, fully automated NAT system for low-to mid-volume laboratories.

In addition to PANTHER, our development pipeline includes NATs to detect:

- human papillomavirus, or HPV, which causes cervical cancer;
- gene-based markers for prostate cancer;
- Trichomonas, a common parasitic STD;
- different types of influenza virus and other respiratory infections; and
- human leukocyte antigens, or HLAs, which are used to determine transplant compatibility.

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 1,300 people.

Recent Acquisition and Disposition Transactions

Acquisition of Tepnel Life Sciences plc

In April 2009, we acquired Tepnel (now known as Gen-Probe Life Sciences Ltd.), a United Kingdom-based international life sciences products and services company, for approximately $137.1 million (based on the then applicable GBP to USD exchange rate). Our acquisition of Tepnel has provided us with growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerated our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe.

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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 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.

Acquisition of Prodesse, Inc.

In October 2009, we acquired Prodesse, a privately held Wisconsin corporation, for approximately $60.0 million, subject to a designated pre-closing operating income adjustment. We may also be required to make additional cash payments to former Prodesse securityholders of up to an aggregate of $25.0 million based on the achievement of certain specified performance measures. Our acquisition of Prodesse has provided us with access to the respiratory and gastrointestinal infectious disease market, which we believe supports our strategic focus on commercializing differentiated molecular tests for infectious diseases.

Sale of BioKits Food Safety Testing Business

In December 2009, we sold our BioKits food safety testing business to Neogen Corporation. This business, which we acquired as part of our acquisition of Tepnel earlier in 2009, includes tests for food allergens, meat and fish speciation, and plant genetics. We believe the divestiture of this business is consistent with our strategic focus on human molecular diagnostic opportunities.

Strategy

We intend to scale our operations 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 infectious diseases, transplant diagnostics and blood screening 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.

In infectious diseases, we expect to develop and commercialize assays for women s health, virology and other infectious diseases. The focus of our women s health strategy will continue to be our chlamydia and gonorrhea business, where we intend to invest in technologies to maintain or expand our market share. We also intend to commercialize our HPV screening assay and related products, with the goal to become one of the leaders in this market over time. In addition, we expect to develop niche assays that expand and complement our product menus. In virology, we intend to pursue internal development programs to establish a leadership position in this market.

Our transplant diagnostics business comprises our 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 develop our technological capabilities.

In blood screening, we partner 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 deploying our PANTHER instrument platform to the collaboration s customer base.

We also intend to expand into adjacent markets within clinical diagnostics, beginning with prostate oncology and companion diagnostics. In prostate oncology, we expect to leverage our in-licensed content to build a sizeable commercial business focused on the urologist. In addition, we intend to expand this business through acquisitions or partnerships that enhance our scale and speed to market. We also intend to build on our capabilities in pharmaceutical services and our expertise in developing genomic markers to partner with therapeutic companies for companion diagnostics in markets that are consistent with our capabilities.

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Competitive Strengths

Assay Development

We believe our core technologies and scientific expertise enable us to develop diagnostic and blood screening assays with superior performance than 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 developing 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. We believe that the use of automated instrumentation, such as our TIGRIS instrument and our development-stage PANTHER instrument, will facilitate growth in both the clinical diagnostics and blood screening portions of the NAT market.

Innovation

As of December 31, 2009, we had 338 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 $106.0 million in 2009, $101.1 million in 2008 and $97.1 million in 2007. Based on these investments, we had more than 500 United States and foreign patents covering our products and technologies as of December 31, 2009. 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 tests to safeguard the nation s blood supply.

Sales and Service

As of December 31, 2009, our direct sales force consisted of 56 employees and a 60 member technical field support group who target customers in the United States, Canada 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 15 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. 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 United States Food and Drug Administration, or FDA, foreign governments, independent standards auditors and customers. Our team of 187 regulatory, clinical and

quality assurance professionals 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

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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 procedures, 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 allows for the detection of the presence of a lower concentration of the target organism and helps 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 infectious diseases, including women s health, virology and other infectious diseases, transplant diagnostics, and blood screening. We are also expanding into adjacent areas where we believe our capabilities could offer sustainable competitive advantage, such as prostate cancer and companion diagnostics.

Infectious Diseases

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 approximately 60% of the total chlamydia and gonorrhea tests sold in the United States in 2009.

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

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so, the American Cancer Society estimates that there were more than 11,000 new cases of invasive cervical cancer in 2007, as well as nearly 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 approximately 2 million of the 50 million Pap tests performed annually in the United States have equivocal results, which are known as ASC-US. These women are often subjected to additional invasive tests, including biopsies, most of which prove negative.

In late 2009, we completed patient enrollment in our U.S. clinical trial for our investigational APTIMA HPV assay. The assay is an amplified nucleic acid test 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 higher amounts when HPV infections progress toward cervical cancer. We believe that targeting these mRNAs may more accurately identify women at higher risk of having, or developing, cervical cancer than competing assays that target HPV deoxyribonucleic acid, or DNA. The APTIMA HPV assay is designed to run on our TIGRIS instrument system and on our future medium-throughput PANTHER instrument.

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 Direct Tube Sampling, or DTS, system.

Trichomonas vaginalis. Trichomonas 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 8 million cases of Trichomonas infection annually in North America, 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 the third quarter of 2009, we began studies to validate our APTIMA *Trichomonas vaginalis* assay on the TIGRIS instrument system to permit registration and sale of the assay in the European Union, or EU, and commenced a U.S. clinical trial for this assay on the TIGRIS instrument 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 epilepsy, cerebral palsy, visual impairment, permanent brain damage and retardation. Our AccuProbe Group B Streptococcus Culture ID Test offers a rapid, non-subjective method for the definitive identification of Group B Streptococcus based on the detection of specific ribosomal RNA sequences.

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 quantity of virus is determined 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 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.

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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. We are currently investigating opportunities to broaden our virology business, and have begun early development work on a quantitative HIV assay that would be designed to run on our investigational PANTHER instrument.

Other Infectious Diseases

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. Several strains of flu, including seasonal flu and the novel H1N1 (swine) flu, circulated in the United States in 2009. 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 H1N1 flu infection, vomiting and diarrhea may also occur. Annual outbreaks of the seasonal flu usually occur during the late fall through early spring. In a typical year, approximately 5 to 20 percent of the population gets the seasonal flu and approximately 36,000 flu-related deaths are reported. Like seasonal flu, illness in people with swine flu can vary from mild to severe. During 2009, a significant number of deaths were reported and associated with swine flu in otherwise healthy individuals, including patients younger than those typically at risk for serious consequences from the seasonal flu. A pandemic flu occurs when a novel influenza virus emerges for which there is little or no immunity in the human population; the virus may cause serious illness and spread easily from person-to-person worldwide. On June 11, 2009, the WHO declared that a global pandemic of H1N1 flu was underway.

Healthcare associated infections, or HCAIs, are a growing problem worldwide. According to the CDC, in American hospitals alone, HCAIs account for an estimated 1.7 million infections and approximately 100,000 deaths annually. One common HCAI is *Clostridium difficile*, often called C. difficile. According to the Mayo Clinic, C. difficile is a bacterium that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon. Illness from C. difficile most commonly affects older adults in hospitals or in long-term care facilities and typically occurs after use of antibiotic medications. In recent years, C. difficile infections have become more frequent, more severe and more difficult to treat. Each year, tens of thousands of people in the United States get sick from C. difficile, including some otherwise healthy people who are not hospitalized or taking antibiotics.

We market and sell ProFlu+, a real-time PCR assay designed to detect influenza A and B and respiratory syncytial virus, or RSV, and ProFlu-ST, a real-time PCR assay designed to detect and differentiate three types of influenza A: seasonal H1, novel 2009 H1N1, and seasonal H3, under our Prodesse product line. ProFlu-ST is currently being sold under an Emergency Use Authorization, or EUA, granted by the FDA because of the swine flu pandemic. The EUA allows the sale of the ProFlu-ST assay for the duration of the public health emergency, which is currently scheduled to expire on April 26, 2010. We intend to file a 510(k) application for ProFlu-ST with the FDA prior to the scheduled expiration of the EUA. Our Prodesse product line also includes ProGastro Cd, a real-time PCR assay for the qualitative detection of toxigenic C. difficile.

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, 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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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. Human leukocyte antigen typing is performed for kidney, bone marrow, liver, pancreas, and heart transplants. The probability that a transplant will be successful increases with the number of identical HLA antigens. Graft rejection occurs when the immune cells (T-lymphocytes) of the recipient recognize specific HLA antigens on the donor s organ as foreign. The T-lymphocytes initiate a cellular immune response that results in graft rejection. Alternatively, T-lymphocytes present in the grafted tissue may recognize the host tissues as foreign and produce a cell-mediated immune response against the recipient. This is called graft versus host disease, or GVHD, and it can lead to life-threatening systemic damage in the recipient. HLA testing is performed to reduce the probability of both rejection and GVHD, and is also used in the ongoing management of transplant recipients.

Tepnel s HLA testing products enable us to diversify into the transplant typing market. Tepnel sells xMAP multiplex assays in the field of transplant diagnostics under its development and supply agreement with Luminex. According to internal market research, the worldwide market for HLA tests was estimated at $260 million in 2008, and is forecast to grow at a low-double-digit rate.

Blood Screening

According to the WHO, each year more than 80 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 response may take some time. 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 and WNV.

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. We have developed diagnostic tests designed to detect markers for prostate cancer. 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. In November 2006, we launched our CE-marked PROGENSA PCA3 assay, a prostate cancer specific molecular diagnostic test, in the European Economic Area. Our ASRs for detection of the PCA3 gene are also available in the United States. ASRs comprise a category of individual reagents utilized by clinical laboratories to develop and validate their own diagnostic tests. We acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure, Inc., or DiagnoCure, in November 2003. In addition, in May 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 August 2009, we began a clinical trial intended to secure U.S. regulatory approval of our PROGENSA PCA3 assay for use on our semi-automated DTS instrument systems.

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Companion Diagnostics

We believe markets will continue to develop for new applications of NAT technology in other clinical and non-clinical fields. Among clinical fields, we believe NAT technology will be used in new applications such as genetic predisposition testing and pharmacogenomics, which involves the study of the relationship between nucleic acid sequence variations in an individual s genome and the individual s response to a particular drug. We expect that nucleic acid assays will be used in the field of pharmacogenomics to screen patients prior to administering new drugs. Many genetic variations are caused by a single mutation in a nucleic acid sequence, a so-called single nucleotide polymorphism, or SNP. Individuals with a specific SNP in a drug metabolism gene may not respond to a drug or may have an adverse reaction to that drug because the body may not metabolize the drug in a normal fashion. We believe the emergence of pharmacogenomics and individually targeted therapeutics will create opportunities for diagnostic companies to develop tests to detect genetic variations that affect responses to drug therapies.

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 family of products integrate three separate technologies, 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, reduce laboratory costs and improve laboratory efficiency. Each of these technologies is described in greater detail below.

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, which 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.

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, which allows the support, with the target bound to it, to 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.

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. HPA has enabled us to produce the first NAT assay that did not require the cumbersome wash steps needed with conventional probe tests and immunoassays. In the HPA process, the acridinium ester, or

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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, we have created NAT assays that can detect two separate targets simultaneously.

Other Product Technologies

Our recent acquisitions of Prodesse and Tepnel 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 Roche 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.

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Key Products

In the tables below we identify some of the key products we offer in the various markets we currently serve.

Infectious Diseases

Women s Health

We have established a market-leading position in non-amplified NAT assays, particularly with respect to assays for the detection of chlamydia and gonorrhea, and we have obtained FDA approvals for amplified STD tests to compete in that 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.
PACE family of assays	Non-amplified NATs to detect chlamydia and gonorrhea.	Marketed globally, including by distributors outside the U.S.
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.	ASRs available in the U.S. through laboratories qualified under CLIA; studies underway in the U.S. and Europe to gain regulatory clearance.
APTIMA HPV assay	Uses APTIMA technology to detect 14 sub-types of high-risk HPV associated with cervical cancer.	Marketed in Europe; U.S. clinical trial underway.
AccuProbe Group B Streptococcus (GBS) assay	Non-amplified NAT to detect GBS from culture.	Marketed globally, including by distributors outside the U.S.

Virology

We market qualitative diagnostic tests designed to determine whether a target virus is present, and quantitative tests that are designed to determine the amount of the virus present in the sample being tested.

Product Line	Description	Availability
APTIMA HIV-1 assay		Marketed globally.

	Uses APTIMA technology to qualitatively detect RNA from HIV-1, the virus that causes AIDS.	
APTIMA HCV assay	Uses APTIMA technology to qualitatively detect RNA from the hepatitis C virus.	Marketed globally (co-marketed with Siemens Healthcare Diagnostics, Inc., or Siemens)).
ASRs for quantitative HCV testing	Analyte specific reagents used by laboratories qualified under CLIA to quantify HCV viral load.	Marketed by Siemens in the U.S.

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Other Infectious Diseases

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

Product Line	Description	Availability
Pro-Flu+	Uses real-time PCR to detect influenza A, B and Respiratory syncytial virus, or RSV.	Marketed globally, including by distributors outside the U.S.
Pro-Flu ST	Uses real-time PCR to detect and differentiate three types of influenza A: seasonal H1, novel 2009 H1N1, and seasonal H3.	Available in the U.S. until April 26, 2010 under FDA Emergency Use Authorization; marketed outside the U.S., including by distributors.
ProGastro Cd	Uses real-time PCR to detect toxigenic strains of *Clostridium difficile.*	Marketed globally, including by distributors outside the U.S.
AMPLIFIED MTD	Uses TMA to detect *Mycobacterium tuberculosis.*	Marketed globally, including by distributors outside the U.S.
GAS Direct	Non-amplified NAT to detect GAS directly from a throat swab.	Marketed globally, including by distributors outside the U.S.

Transplant Diagnostics

As a result of our acquisition of Tepnel in April 2009, we now offer certain products in the transplant diagnostics field, 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 LifeScreen antibody screening kits	Uses the multiplex Luminex xMAP platform to screen for the presence of HLA antibodies in transplant patients.	Marketed globally.

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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 target capture, TMA 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 detect 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 U.S. by Novartis
Procleix WNV assay	Amplified NAT to detect West Nile Virus in donated blood, plasma, organs and tissues.	Marketed globally by Novartis.

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 and APTIMA GC, 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	Marketed globally, including by distributors outside the U.S. and by

	instruments. Approved to run a number of infectious disease and blood screening assays. In blood screening, also known as the PROCLEIX system, or eSAS.	Novartis in the blood screening market.
PANTHER	Integrated, fully automated testing instrument for low- to mid-volume laboratories.	In development and not yet commercially available.

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Prostate Oncology

In November 2006, we CE-marked our PROGENSA PCA3 assay, allowing it to be marketed in the European Economic Area. 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 extremely 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 currently plan to modify our existing PCA3 assay for use with our investigational PANTHER instrument system.

Product Line	Description	Availability
PROGENSA PCA3	Uses APTIMA technology to detect the PCA3 gene that is over-expressed by cancerous prostate tissue.	Marketed outside the U.S., including by distributor in Japan.
PCA3 ASRs	Analyte specific reagents used by laboratories qualified under CLIA to detect the PCA3 gene that is over-expressed by cancerous prostate tissue.	ASRs available in the U.S. through laboratories qualified under CLIA; clinical studies commenced in August 2009 to obtain FDA regulatory approval for sale within the U.S.

Customers

The primary customers for our clinical diagnostic products include large reference laboratories, public health institutions and hospitals. Our blood screening collaboration with Novartis accounted for 42% of our total revenues in 2009 and 48% of our total revenues in 2008. Our blood screening collaboration with Novartis is largely dependent on two large customers in the United States, The American Red Cross and America s Blood Centers, 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 2009.

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 and certain countries in Europe through our direct sales force. In other countries outside the United States, we rely on distributors for our clinical diagnostic products. As of December 31, 2009, our direct sales force consisted of a staff of 56 sales employees and a staff of 60 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 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. Our blood screening products are marketed and distributed worldwide by Novartis.

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Distributors

We have an agreement with bioMérieux S.A., or bioMérieux, for distribution of certain of our microbial non-viral diagnostic products in Europe and various countries in Asia (other than Japan), Australia, South America and Mexico. We have an agreement for distribution of our microbial non-viral diagnostic products in Japan with Fujirebio, Inc., or Fujirebio. In other countries, we utilize independent distributors with experience and expertise in clinical diagnostic products.

The blood screening products we manufacture under our collaboration agreement with Novartis are marketed and distributed solely by Novartis. 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.

Key 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, 2009, we incurred a total of $14.7 million in expenses under this agreement, including $3.0 million in expenses during 2009. 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 (now Qiagen Gaithersburg, Inc.), filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution, or ICDR, 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 is null and void. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. The ruling issued by the ICDR in 2009 rejected all claims asserted by Digene and 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. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued.

Virology

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

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combination of transfer prices and royalties on sales of the HCV assays and reagents. We recognized $1.1 million in revenue during 2009 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 are 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 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. The parties have also agreed to evaluate, using our technologies, the development of companion diagnostics for current or future Novartis medicines. Novartis has agreed to provide certain funding to us in support of initial research and development in this area.

From inception through December 31, 2009, we recognized a total of $1.3 billion in revenue under our collaboration with Novartis and had recorded $2.3 million in deferred license revenues as of December 31, 2009.

Prostate Cancer

Exclusive License with DiagnoCure. In November 2003, we entered into a license and collaboration 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 commenced paying these royalties 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 further amended our license and collaboration agreement with DiagnoCure. Pursuant to this amendment, our exclusive license in the United States with respect to the licensed PCA3 marker will 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 and

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collaboration agreement. We currently plan to modify our existing PCA3 assay for use with our investigational PANTHER instrument system.

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 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 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.

Research Agreement with GSK. In June 2005, we entered into a research agreement with SmithKline Beecham Corporation, doing business as GlaxoSmithKline, and SmithKline Beecham (Cork) Ltd., together referred to as GSK. Under the terms of the agreement, we agreed to provide GSK our investigational PCA3 assay to test up to 6,800 clinical samples obtained from patients enrolled in GSK s REDUCE™ (REduction by DUtasteride of prostate Cancer Events) clinical trial, which is designed to determine the efficacy and safety of GSK s drug dutasteride (AVODART) in reducing the risk of prostate cancer in men at increased risk of this disease. We agreed to reimburse GSK for expenses that GSK incurs for sample collection and related processes during the four-year prospective clinical trial. We also agreed to provide the PCA3 assay without charge and to pay third party clinical laboratory expenses for using the assay to test the samples. The agreement terminates on the earlier of six years from the commencement date or two years after certain clinical data is unblinded. GSK may terminate the agreement upon notice to us and we may terminate the agreement on specific dates provided certain conditions are met. Each party may also terminate the agreement for material breaches and in certain other limited circumstances. The agreement was amended in 2007 to expand its scope and include testing with our investigational assay for the TMPRSS gene fusion. We expect that initial data from this clinical trial with respect to PCA3 will be presented in 2010.

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. The development agreement provides for the development of a fully automated, mid-volume molecular diagnostic instrument by Stratec. Stratec is providing services for the design and development of the PANTHER instrument system at a fixed price of $9.4 million, to be paid in installments due upon achievement of specified technical milestones. In addition, we will purchase prototype, validation, pre-production and production instruments, at specified fixed transfer prices set forth in the development agreement.

The development agreement provides that until 90 days following our acceptance of prototype PANTHER instruments, we have the right to terminate the agreement on limited, specified conditions, upon 30 days written notice and payment of specified termination compensation. 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. Each of our rights and obligations under the supply agreement is contingent upon successful completion of the parties

activities under the development agreement. The supply agreement has an initial term of 10 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.

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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.

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, 2009, we owned more than 500 issued United States and foreign patents. In addition, our patent portfolio includes pending patent applications in the United States and corresponding international filings in major industrial nations. The last of our currently issued patents will expire by December 15, 2028. 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.

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, and 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 instrument. In addition, other companies, including Beckman Coulter, Inc., 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.

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

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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 merger with 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. Our blood screening products generally are classified in the United States as biologics and are regulated by the FDA s Center for Biologics Evaluation and Research.

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 premarket approval application, or PMA, which requires human clinical trials. Clinical trials must be conducted in accordance with Good Clinical Practice under protocols generally submitted to 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 clearances or approvals, withdrawals or suspensions of current product applications, suspension of export certificates and criminal prosecution.

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 preclinical 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 proposed biologic s 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,

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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 authorization, pricing and reimbursement vary widely from country to country. Our 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.

Manufacturing and Raw Materials

We own two state-of-the-art 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 the FDA s Center for Biologics Evaluation and Research for the production of blood screening products. In the U.S we also have manufacturing facilities in Stamford, Connecticut and Waukesha, Wisconsin.

Outside of the U.S., we have manufacturing facilities in Cardiff and Abingdon in the United Kingdom, as well as in Besancon, France. 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 is the only manufacturer of our TIGRIS instrument. We have no firm long-term commitments from KMC Systems or any of our other manufacturers to supply products 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

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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, 2009, we had 1,250 full-time employees, of whom 288 hold advanced degrees, and 67 temporary employees. Of those employees, 338 were in research and development, 187 were in regulatory, clinical and quality systems, 232 were in sales and marketing, 211 were in general and administrative and 349 were in operations. None of our employees is covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Geographic Information

For geographic information regarding our revenues, see Note 15 to the Consolidated Financial Statements included in Part II, Item 8 of 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 for blood screening tests 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 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 project future sales, prices and the sales cycles accurately. 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 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. 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. Furthermore, failure to achieve our operational goals may inhibit our targeted growth plans and the successful implementation of our strategic objectives.

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. We do not believe we have experienced recent declines in overall blood screening or clinical diagnostics customer purchases as a result of current economic conditions. However, these effects are difficult to identify and a continued weakening of the global and domestic economies, or a reduction in customer spending or credit availability, could result in downward pricing pressures, delayed or decreased purchases of our

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products and longer sales cycles. 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 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 40% and 44% of our total revenues for 2009 and 2008, 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 rely upon bioMérieux for distribution of certain of our products in most of Europe and Australia, Fujirebio for distribution of certain of our products in Japan, and various independent distributors for distribution of our products in other regions. Distribution rights revert back to us upon termination of the distribution agreements. Our distribution agreements with Fujirebio and bioMérieux expire in December 2010 and May 2012, respectively, although each agreement may terminate earlier under certain circumstances.

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 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.

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 collaboration with Novartis with respect to blood screening would have a material adverse effect on our business.

We rely, to a significant extent, on our corporate collaborators for funding development and for marketing 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 November 2007, for example, 3M informed us that it no longer intended to fund our collaboration to develop rapid molecular assays for the food testing industry. We and 3M subsequently terminated this agreement. In June 2008, 3M discontinued our collaboration to develop assays for healthcare-associated infections.

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

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those under our agreements with Novartis and Siemens, 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 also intend to pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. We have limited experience in acquiring other companies. 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 completed the acquisition of Tepnel for approximately $137.1 million (based on the then applicable GBP to USD exchange rate). We believe the Tepnel acquisition provides us with access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerates our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe. In addition, in October 2009 we acquired Prodesse, which we believe supports our strategic focus on commercializing differentiated molecular tests for infectious diseases. Our beliefs regarding the merit of these acquisitions are based upon numerous assumptions that are subject to risks and uncertainties that could deviate materially from our estimates, and could adversely affect our operating results.

Managing the acquisitions of Tepnel and Prodesse, 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;
- 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

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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, especially in light of current economic conditions.

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 development-stage PANTHER instrument system on a timely basis could have a negative impact on our financial performance.

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 we may develop 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 impact our growth objectives and financial performance.

In October 2006 and May 2007, the FDA granted marketing approval for use of the Procleix Ultrio assay on our enhanced semi-automated system, or eSAS, and TIGRIS, respectively, to screen donated blood, plasma, organs and tissue for HIV-1 and HCV in individual blood donations or in pools of up to 16 blood samples. In August 2008, the FDA approved the Procleix Ultrio assay to also screen donated blood, plasma, organs and tissues for HBV in individual blood donations or in pools of up to 16 blood samples on eSAS and the TIGRIS system. However, the FDA s current requirements for testing blood donations do not mandate testing for HBV DNA. At its April 2009 meeting, the FDA s Blood Products Advisory Committee, or BPAC, considered various issues concerning HBV NAT testing of donated blood. Although we believe the BPAC discussion supported the utility of NAT testing for HBV, no formal recommendation was made to make such testing mandatory at the meeting. We believe blood screening centers will continue to focus on improving the safety of donated blood by adopting the most advanced blood screening technologies available. For example, we believe most of our U.S. blood screening customers have adopted the Procleix Ultrio assay. However, if some customers do not transition to the use of the Procleix Ultrio assay at expected levels for any of these or other reasons, our financial performance may be adversely affected.

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, 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

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product line offerings. Our existing competitors or new market entrants may be in 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, 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 also may compete with viral inactivation or reduction technologies and blood substitutes.

We believe the global blood screening market is maturing rapidly, potentially accelerated by the world s macroeconomic conditions. 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

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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 the quality thereof 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. We are currently involved in proceedings with Digene (now Qiagen Gaithersburg, Inc.) regarding our supply and purchase agreement with Roche Molecular Systems. In December 2006, Digene filed a demand for binding arbitration against Roche with the ICDR 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 is null and void. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. The ruling issued by the ICDR in 2009 rejected all claims asserted by Digene and 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. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued.

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. is the only manufacturer of our LEADER series of luminometers. 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, MGM Instruments or any of our other manufacturers 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 or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its manufacturing operations or becomes insolvent, 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 increase our volumes or to 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

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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. If we are required or elect to change contract manufacturers, we may lose revenues and our customer relationships may suffer.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in commercializing, or be unable to commercialize, our products as a result of, these regulations.

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. 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 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 authorization, pricing and reimbursement vary widely from country to country. Our European Union (EU) foreign marketing authorizations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

The process of seeking and obtaining regulatory approvals, particularly from the FDA and some foreign governmental authorities, to market our products can be costly and time consuming, and approvals might not be granted for future products on a timely basis, if at all. In March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. If we experience unexpected complications in conducting the trial, we may incur additional costs or experience delays or difficulties in receiving FDA approval. For example, we originally expected that enrollment and testing of approximately 7,000 women would be required to complete this trial. However, we actually enrolled approximately 13,000 women in the trial based on the actual prevalence of cervical disease observed. Although we completed enrollment in the trial late in 2009, we cannot provide any assurances that the FDA will ultimately approve the use of our APTIMA HPV assay upon completion of the trial. Failure to obtain or delay in obtaining FDA approval of our APTIMA HPV assay could have a material adverse effect on our financial performance. In the third quarter of 2009, we began studies to validate our APTIMA *Trichomonas vaginalis* assay on the TIGRIS instrument system to permit registration and sale of the assay in the EU, as well as commenced a U.S. clinical trial for the *Trichomonas* assay on the TIGRIS instrument system. We cannot provide any assurances that the *Trichomonas* assay will be approved for sale. In addition, we commenced a U.S. clinical trial in the third quarter of 2009 for our CE-marked PROGENSA PCA3 assay; however, there can be no assurance that this assay will be approved for sale in the United States.

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 the 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 mRNA and for use in the detection of the parasite *Trichomonas vaginalis.* We also have developed an ASR for quantitative

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HCV testing that Siemens provides to Quest Diagnostics. 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.

The use of our diagnostic products is also affected by CLIA, and related federal and state regulations that provide for regulation of 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.

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.

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 a voluntary recall, and any such recall could divert managerial and financial resources, could be more difficult and costly to correct, could result in the suspension of sales of our products and could harm our financial results and our reputation.

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

We currently receive revenues from the sale of blood screening assays primarily for use with pooled donor samples. 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 on a per donation basis, our profit margins are greater when a single test can be used to screen multiple donor samples.

We believe certain blood screening markets are trending from pooled testing of large numbers of donor samples to smaller pool sizes. A greater number of tests will be required in markets where smaller pool sizes are required. Under our amended and restated 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 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. We have already observed this trend with respect

to certain sales internationally. 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, because we do not know the ultimate selling price that Novartis would charge to the end user or the degree to which smaller pool size testing will be adopted across the markets in which our products are sold.

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Because we depend on a small number of customers for a significant portion of our total revenues, 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 has accounted for a significant portion of our total revenues, and we do not have any long-term commitments with these customers, other than our collaboration agreement with Novartis. Total revenues from our blood screening collaboration with Novartis, which include product sales, collaborative research revenues and royalties, accounted for 42% and 48% of our total revenues for 2009 and 2008, respectively. Our blood screening collaboration with Novartis is largely dependent on two large customers in the United States, The American Red Cross and America s Blood Centers, 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 in each of 2009 and 2008. However, various state and city public health agencies accounted for an aggregate of 8% of our total revenues for both 2009 and 2008. Although state and city public health agencies are legally independent of each other, we believe they tend to act similarly with respect to their product purchasing decisions. 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 development of blood screening and clinical diagnostic products and instruments. Although we had more than 500 United States and foreign patents covering our products and technologies as of December 31, 2009, 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 December 15, 2028 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.

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 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

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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.

Recently, we have been involved in a number of patent-related disputes with third parties. In December 2006, Digene (now Qiagen Gaithersburg, Inc.) filed a demand for binding arbitration against Roche with the ICDR 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 our supply and purchase agreement with Roche is null and void. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. The ruling issued by the ICDR in 2009 rejected all claims asserted by Digene and 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. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued.

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. Finally, the complaint alleges that BD has infringed our U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified. The complaint seeks monetary damages and injunctive relief. There can be no assurances as to the final outcome of the 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 National Institutes of Health, or 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 are informed that the Patent and Trademark Office determined that Institut Pasteur invented the subject matter at issue prior to NIH and Novartis. We are also informed that Novartis and NIH subsequently filed actions in the United States District Court for the District of Columbia challenging the decisions of the Patent and Trademark

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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 United States 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.

Health care reform initiatives could adversely affect our business, profitability and stock price.

The current U.S. administration has proposed a number of initiatives to reform health care. The U.S. Congress debated health care reform legislation in recent months, and may consider legislation again in the future. Although we cannot predict how pending or future legislative and regulatory proposals might affect our business, we are aware that certain legislation proposed in the U.S. House of Representatives and the U.S. Senate included a tax on medical devices, which would likely include assays and instruments we sell. The details of any such proposed tax, including how such a tax would be calculated and assessed, are not currently clear. However, we generally believe that any such tax, if adopted as part of overall health care reform legislation or otherwise, would increase our tax burden and reduce our profitability, 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 N.A., or 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. 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. In April 2009, we borrowed an additional $70.0 million under the revolving credit facility, bringing the total principal amount outstanding to $240.0 million as of December 31, 2009. In February 2010, our credit agreement with Bank of America was amended to extend the maturity date to February 2011.

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 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, we believe that no such defense is available for our 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,

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development, manufacture and marketing of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could result in an increase of 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 no insurance coverage, in which case we may have to pay the entire amount of any award. In addition, insurance varies in cost and can be difficult to obtain, and we may not be able to obtain insurance in the future on terms acceptable to us, or at all. A successful product liability claim brought against us in excess of our insurance coverage, or which our insurance policies do not cover, may require us to pay substantial amounts, which could harm our business and results of operations.

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

As of December 31, 2009, we had approximately $464.9 million of long-lived assets, including $12.6 million of capitalized software, net of accumulated amortization, relating to our TIGRIS and PANTHER instruments, goodwill of $122.2 million, a $5.4 million investment in Qualigen, Inc., or Qualigen, a $5.0 million investment in DiagnoCure, a $0.7 million investment in Roka, and $161.5 million of capitalized licenses and manufacturing access fees, patents, purchased intangibles and other long-term assets. Additionally, we had $72.2 million of land and buildings, $22.3 million of building improvements, $62.5 million of equipment and furniture and fixtures and $0.5 million in construction in progress. The substantial majority of our long-lived assets are located in the United States. The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable.

These events or changes might include a significant decline in market share, a significant decline in profits, rapid changes in technology, significant litigation, an inability to successfully deliver an instrument to the marketplace and attain customer acceptance or other matters. Adverse events or changes in circumstances may affect the estimated undiscounted future operating cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. In the past we have incurred, and in the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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

A change in accounting standards or practices, or a change in existing taxation rules or practices, can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. Our effective tax rate can also be impacted by changes in estimates of prior years items, past and future levels of research and development spending, the outcome of audits by federal, state and foreign jurisdictions and changes in overall levels of income before tax.

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

In recent years, we have incurred significant costs in connection with the development of blood screening and clinical diagnostic products, as well as our TIGRIS and PANTHER instrument systems. We expect our expense levels to

remain high in connection with our research and development as we seek to continue to expand our product offerings and continue to develop products and technologies in collaboration with our partners. As a result, we will need to continue to generate significant revenues to maintain current levels of profitability. Although we expect that our research and development expenses as a percentage of revenue will decrease in future periods, we may not be

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able to generate sufficient revenues to maintain current levels of profitability in the future. A potential reduction of profitability in the future could cause the market price of our common stock to decline.

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

We engage one or more third parties to manage some of our cash consistent with an investment policy that restricts investments to securities of high credit quality, with requirements placed on maturities and concentration by security type and issue. These investments are intended to preserve principal while providing liquidity adequate to meet our projected cash requirements. Risk of principal loss is intended to be minimized through diversified short and medium term investments of high quality, but these investments are not, in every case, guaranteed or fully insured. In light of recent changes in the credit market, some high quality short term investment securities, similar to the types of securities that we invest in, have suffered illiquidity, events of default or deterioration in credit quality. If our short term investment portfolio becomes affected by any of the foregoing or other adverse events, we may incur losses relating to these investments.

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

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

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

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

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

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

The amplified NAT tests that we produce are significantly more expensive to manufacture than our non-amplified products. As we continue to develop new amplified NAT tests in response to market demands for greater sensitivity, our product costs will increase significantly and our margins may decline. We sell our products in a number of cost-sensitive market categories, and we may not be able to manufacture these more complex amplified tests at costs that would allow us to maintain our historical gross margin percentages. In addition, new products that detect or quantify more than one target organism will contain significantly more

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complex reagents, which will increase the cost of our manufacturing processes and quality control testing. We or other parties we engage to help us may not be able to manufacture these products at a cost or in quantities that would make these products commercially viable. If we are unable to develop or contract for manufacturing capabilities on acceptable terms for our products under development, we will not be able to conduct pre-clinical, clinical and validation testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates.

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

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 26% and 23% of our total revenues for 2009 and 2008, respectively. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 60% and 78% of our international revenues for 2009 and 2008, respectively.

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

- the imposition of government controls;
- export license requirements;
- economic and political instability;
- price controls;
- trade restrictions and tariffs;
- differing local product preferences and product requirements; and
- changes in foreign medical reimbursement and coverage policies and programs.

In addition, we anticipate that requirements for smaller pool sizes of blood samples will result in lower gross margin percentages, as additional tests are required to deliver the sample results. We have already observed this trend with respect to certain sales in Europe. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion has led and will continue to lead to lower gross margin percentages.

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

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

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

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

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

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

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

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

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

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

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

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If a natural or man-made disaster strikes our manufacturing facilities, we will be unable to manufacture our products for a substantial amount of time and our sales will decline.

We manufacture substantially all of our products in four manufacturing facilities, two of which are located in San Diego, California and the others are located in Stamford, Connecticut and Waukesha, Wisconsin. These facilities and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. Our facilities may be harmed by natural or man-made disasters, including, without limitation, earthquakes and fires, and in the event they are affected by a disaster, we would be forced to rely on third-party manufacturers. The wildfires in San Diego in October 2007 required that we temporarily shut down our facility for the manufacture of blood screening products. In the event of a disaster, we may lose customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

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

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

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

- divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms;
- limit the right of stockholders to remove directors;
- regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders; and
- authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

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

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

Growth in our business has placed and may continue to place a significant strain on our personnel, facilities, management systems and resources. We will need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce. In addition, we will have to maintain close

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coordination among our various departments and locations. If we fail to effectively manage our growth, it could adversely affect our ability to pursue business opportunities and expand our business.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have implemented an enterprise resource planning software system to replace our various legacy systems. To more fully realize the potential of this system, we are continually reassessing and upgrading processes and this may be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the operation of this system or any future systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flow and to otherwise operate our business, all of which could adversely affect our financial results, stock price and reputation.

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

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

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our worldwide headquarters are located in our two adjacent facilities located on Genetic Center Drive in San Diego, California. We own each of the facilities and the underlying land. The first facility is 262,000 square feet. The second facility consists of a 292,000 square foot shell, with approximately 217,000 square feet built-out with interior improvements in the first phase. The remaining expansion space can be used to accommodate future growth.

In February 2008, we completed the purchase of the facility where we manufacture our blood screening products. We had previously leased this facility, which consists of 93,646 square feet, located in San Diego, California, since November 1997. The purchase price was $15.7 million.

We also lease a 37,000 square foot facility in Stamford, Connecticut, which functions as the base of our HLA testing products business that we acquired in connection with our acquisition of Tepnel in April 2009. The lease currently runs through April 2015.

In addition, we own a 23,000 square-foot facility in Cardiff, United Kingdom and an 18,000 square-foot facility in Livingston, United Kingdom, as well as lease space in the following locations: Abingdon, United Kingdom; Manchester, United Kingdom; Antwerp, Belgium; Besancon, France; Wiesbaden, Germany; and Waukesha, Wisconsin.

Item 3. ***Legal Proceedings***

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

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Digene Corporation

In December 2006, Digene filed a demand for binding arbitration against Roche, with the ICDR of the American Arbitration Association in New York. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. Digene s arbitration demand challenged the validity of the February 2005 supply and purchase agreement between us and Roche. Under the supply and purchase agreement, Roche manufactures and supplies us with HPV oligonucleotide products. Digene s demand 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 is null and void.

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. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued. We will record the $2.9 million as an offset to general and administrative expense upon cash receipt.

Becton, Dickinson and Company

In October 2009, we filed a complaint for patent infringement 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. Finally, the complaint alleges that BD has infringed our U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified. The complaint seeks monetary damages and injunctive relief. There can be no assurances as to the final outcome of the litigation.

Quidel Corporation

In October 2009, Quidel Corporation, or Quidel, filed a complaint against Prodesse in San Diego County Superior Court, alleging that an advertisement for Prodesse s ProFlu+ Multiplex real-time PCR assay was false and misleading. The complaint sought money damages and injunctive relief based on claims for unfair competition, false advertising, and violation of the Lanham Act. In December 2009, Quidel dismissed the complaint without prejudice, in connection with an agreement by the parties limiting re-publication of the specific advertisement at issue.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the quarter ended December 31, 2009.

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PART II

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

Market Information

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

2008	High	Low
First Quarter	$ 64.68	$ 44.82
Second Quarter	$ 58.71	$ 46.84
Third Quarter	$ 62.39	$ 46.58
Fourth Quarter	$ 54.86	$ 30.01

2009	High	Low
First Quarter	$ 47.11	$ 37.50
Second Quarter	$ 49.29	$ 40.66
Third Quarter	$ 43.63	$ 35.70
Fourth Quarter	$ 45.24	$ 40.50

As of February 16, 2010, there were 6,189 stockholders of record of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

Issuer Purchases of Equity Securities

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
October 1-31, 2009	4,268	$ 44.70		

November 1-30, 2009	14,214	42.11
December 1-31, 2009	83	42.07
Total[(1)]	18,565	42.71

(1) During the fourth quarter of 2009, we repurchased and retired 18,565 shares of our common stock, at an average price of $42.71, withheld by us to satisfy employee tax obligations upon vesting of restricted stock and deferred issuance restricted stock awards granted under our 2003 Incentive Award Plan. We may make similar repurchases in the future to satisfy employee tax obligations upon vesting of restricted stock. As of December 31, 2009, we had an aggregate of 187,405 shares of restricted stock and 60,000 shares of deferred issuance restricted stock awards outstanding.

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

SELECTED FINANCIAL INFORMATION

The selected financial data set forth below with respect to our consolidated statements of income for each of the three years in the period ended December 31, 2009 and with respect to our consolidated balance sheets, at December 31, 2009 and 2008 are derived from our consolidated financial statements that have been audited by Ernst & Young LLP, independent registered public accounting firm, which are included elsewhere in this report. The statement of income data for the years ended December 31, 2006 and 2005 and the balance sheet data as of December 31, 2007, 2006, and 2005 are derived from our audited consolidated financial statements that are not included in this report. The selected financial information set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this report.

	2009	2008	2007	2006	2005
	(In thousands, except per share data)				
Statement of income data for the years ended December 31:					
Revenues:					
Product sales	$ 483,759	$ 429,220	$ 370,877	$ 325,307	$ 271,650
Collaborative research revenue	7,911	20,581	16,619	15,937	25,843
Royalty and license revenue	6,632	22,894	15,518	13,520	8,472
Total revenues	498,302	472,695	403,014	354,764	305,965
Operating expenses:					
Cost of product sales	152,393	128,029	119,641	103,882	83,900
Acquisition-related intangible amortization	4,144				
Research and development	105,970	101,099	97,144	84,545	71,846
Marketing and sales	53,853	45,850	39,928	37,096	31,145
General and administrative	61,828	52,322	47,007	44,936	32,107
Total operating expenses	378,188	327,300	303,720	270,459	218,998
Income from operations	120,114	145,395	99,294	84,305	86,967
Net income[1]	$ 91,783	$ 106,954	$ 86,140	$ 59,498	$ 60,089
Net income per share:					
Basic	$ 1.82	$ 1.98	$ 1.62	$ 1.15	$ 1.19
Diluted	$ 1.79	$ 1.95	$ 1.58	$ 1.12	$ 1.15
Weighted average shares outstanding[2]:					
Basic	50,356	53,740	52,860	51,637	50,617
Diluted	50,965	54,785	54,355	53,200	52,445
Balance sheet data as of December 31:					
Cash, cash equivalents and current marketable securities[3]	$ 485,606	$ 431,398	$ 395,417	$ 159,406	$ 107,686
Working capital[3]	331,182	506,457	480,321	211,555	149,773

Total assets	1,138,567	869,531	789,053	623,839	510,236
Long-term obligations	13,183	2,162	1,893	1,211	250
Stockholders equity[4][5]	767,175	813,760	738,040	570,208	447,373

(1) We adopted Financial Accounting Standards Board, or FASB, guidance on stock-based compensation on January 1, 2006. For 2005, net income including pro forma stock-based compensation expense was $45.3 million ($0.86 per diluted share).

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

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(3) In 2009, we began reporting investments that are in an unrealized loss position deemed to be temporary with a contractual maturity of greater than 12 months as non-current marketable securities. Prior year amounts have been reclassified to conform with the current year presentation.

(4) Effective January 1, 2006, we increased beginning retained earnings by $3.9 million due to adoption of FASB guidance on the effects of prior year misstatements on current year financial statements.

(5) Effective January 1, 2007, we reduced beginning retained earnings by approximately $1.0 million due to adoption of FASB guidance on accounting for uncertainty in income taxes.

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

Overview

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

We market a broad portfolio of products to detect infectious microorganisms, including those causing STDs, TB, 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.

In 2009, we expanded our portfolio of products with acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse added a portfolio of real-time PCR products for detecting influenza and other infectious organisms.

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

Several of our current and future molecular tests can be performed on our TIGRIS instrument, the only fully automated, high-throughput NAT system for diagnostics and blood screening. We are building on the success of our TIGRIS instrument system by developing our next-generation PANTHER instrument, which is designed to be a versatile, fully automated NAT system for low-to mid-volume laboratories.

In addition to PANTHER, our development pipeline includes NATs to detect:

HPV, which causes cervical cancer;

gene-based markers for prostate cancer;

Trichomonas, a common parasitic STD;

different types of influenza virus and other respiratory infections; and

HLAs, which are used to determine transplant compatibility.

Recent Events

Financial Results

Product sales for 2009 were $483.8 million, compared to $429.2 million in 2008, an increase of 13%. Total revenues for 2009 were $498.3 million, compared to $472.7 million in 2008, an increase of 5%. Net income for 2009 was $91.8 million ($1.79 per diluted share), compared to $107.0 million ($1.95 per diluted share) in 2008, a decrease of 14%.

Our total revenues, net income and fully diluted earnings per share in 2009 included $8.5 million of additional one-time revenue associated with the renegotiation of our collaboration agreement with Novartis, as well as the results of operations of Tepnel and Prodesse beginning in April and October of 2009, respectively. In contrast, our

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total revenues, net income and fully diluted earnings per share in 2008 included $16.4 million in royalty and license revenue associated with a third and final settlement payment from Siemens which was recorded in the first quarter of 2008, and a $10.0 million development milestone paid by Novartis, which was recorded in the third quarter of 2008.

Recent Acquisition and Disposition Transactions

Acquisition of Tepnel Life Sciences plc

In April 2009, we acquired Tepnel, a UK-based international life sciences products and services company, for approximately $137.1 million (based on the then applicable GBP to USD exchange rate). Our acquisition of Tepnel has provided us with growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerates our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe. The results of Tepnel s operations have been included in our consolidated statements of income since the date of acquisition.

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

In September 2009, we spun-off our industrial testing assets to Roka, a newly formed private company. In consideration for our contribution of assets 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.

Acquisition of Prodesse, Inc.

In October 2009, we acquired Prodesse, a privately held Wisconsin corporation, for approximately $60.0 million, subject to a designated pre-closing operating income adjustment. We may also be required to make additional cash payments to former Prodesse securityholders of up to an aggregate of $25.0 million based on the achievement of certain specified performance measures. Our acquisition of Prodesse has provided us with access to the respiratory and gastrointestinal infectious disease market, which we believe supports our strategic focus on commercializing differentiated molecular tests for infectious diseases. The results of Prodesse s operations have been included in our consolidated statements of income since the date of acquisition.

Sale of BioKits Food Safety Testing Business

In December 2009, we sold our BioKits food safety testing business to Neogen Corporation. This business, which we acquired as part of our acquisition of Tepnel earlier in 2009, includes tests for food allergens, meat and fish speciation, and plant genetics. We believe the divestiture of this business is consistent with our strategic focus on human molecular diagnostic opportunities.

Stock Repurchase Programs

In August 2008, our Board of Directors authorized the repurchase of up to $250.0 million of our common stock over the two year period following adoption of the program, 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 2009, repurchasing and retiring approximately 5,989,000 shares since the program s inception at an average price of $41.72, or approximately $249.8 million in total.

In February 2010, our Board of Directors authorized the repurchase of up to $100.0 million of our common stock over the one year period following adoption of the program, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program.

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Corporate Collaborations

Novartis

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 are 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 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. The parties have also agreed to evaluate, using our technologies, the development of companion diagnostics for current or future Novartis medicines. Novartis has agreed to provide certain funding to us in support of initial research and development in this area.

Critical accounting policies and estimates

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

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

Revenue recognition

We record shipments of our clinical diagnostic products as product sales when the product is shipped and title and risk of loss has passed and when collection of the resulting receivable is reasonably assured.

We manufacture blood screening products according to demand specifications of Novartis. Upon shipment to Novartis, we recognize blood screening product sales at an agreed upon transfer price and record the related cost of products sold. Based on the terms of our collaboration agreement with Novartis, our ultimate share of the net revenue from sales to the end user is not known until reported to us by Novartis. We then adjust blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting our ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized. We amended our agreement with Novartis effective as of January 1, 2009 to decrease the time period between product sales and net payment of our share of blood screening assay revenue from 45 days to 30 days.

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Generally, we provide our instrumentation to reference laboratories, public health institutions and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, we recover the cost of providing the instrumentation in the amount we charge for our diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

We sell our instruments to Novartis for use in blood screening and record these instrument sales upon delivery since Novartis is responsible for the placement, maintenance and repair of the units with its customers. We also sell instruments to our clinical diagnostics customers and record sales of these instruments upon delivery and receipt of customer acceptance. Prior to delivery, each instrument is tested to meet Gen-Probe s and FDA specifications, and is shipped fully assembled. Customer acceptance of our clinical diagnostic instrument systems requires installation and training by our technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating, and testing the instrumentation.

We record shipments of our blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue. This is done because price restrictions apply to these products prior to FDA marketing approval in the United States and similar approvals in foreign countries. Upon shipment of FDA-approved and labeled products following regulatory approval, we classify sales of these products as product sales in our consolidated financial statements.

We record revenue on our research product sales upon delivery of the goods and on our research services in the period during which the related costs are incurred, or services are provided. These revenues consist of outsourcing services for pharmaceutical, biotechnology, and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

We analyze each element of our collaborative arrangements to determine the appropriate revenue recognition. We recognize revenue on up-front payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. According to FASB guidance, revenue arrangements with multiple deliverables are divided into separate units of accounting if (i) the delivered item has stand-alone value, (ii) the vendor has objective and reliable evidence of fair value of the undelivered item(s), and (iii) the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item(s) is probable and substantially within the vendor s control. All of these criteria must be met in order for a delivered item to be accounted for as a separate unit.

We recognize collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the applicable contracts. Non-refundable license fees are recognized over the related performance period or at the time that we have satisfied all performance obligations. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) we have earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement, (iii) the fees are non-refundable, and (iv) performance obligations after the milestone achievement will continue to be funded by the collaborator at a level comparable to the level before the milestone achievement. Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheets.

Royalty revenue is recognized related to the sale or use of our products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual

royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the applicable licensee.

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Income taxes

Our income tax returns are based on calculations and assumptions that are subject to examination by various tax authorities. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of these examinations and any future examinations in determining the adequacy of our provision for income taxes. As part of our assessment of potential adjustments to our tax returns, we increase our current tax liability to the extent an adjustment would result in a cash tax payment or decrease our deferred tax assets to the extent an adjustment would not result in a cash tax payment. We review, at least quarterly, the likelihood and amount of potential adjustments and adjust the income tax provision, the current tax liability and deferred taxes in the period in which the facts that give rise to a revision become probable and estimable. Although we believe that the estimates and assumptions supporting our assessments are reasonable, adjustments could be materially different from those that are reflected in historical income tax provisions and recorded assets and liabilities.

We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical taxable income, projected future taxable income, the expected timing of the reversals of existing temporary differences and the implementation of tax-planning strategies.

Stock-based compensation

We grant options to purchase our common stock to our employees and directors under our equity compensation plans. Eligible employees can also purchase shares of our common stock at 85% of the lower of the fair market value on the first or the last day of each six-month offering period under our Employee Stock Purchase Plan, or ESPP. The benefits provided under these plans are share-based payments and stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period on a straight-line basis. As of December 31, 2009, there were no outstanding equity awards with market or performance conditions. We began using a modified prospective application on January 1, 2006. Accordingly, prior periods have not been revised for comparative purposes. Stock-based compensation expense recognized is based on the value of share-based payment awards that are ultimately expected to vest, which coincides with the award holder s requisite service period.

We estimate the value of our share-based payment awards using the Black-Scholes-Merton option-pricing model, and amortize all new grants as expense on a straight-line basis over the vesting period. Also, a portion of these costs are capitalized into inventories on our balance sheet, and are recognized as expense when the related products are sold.

Our stock options and the option component of our ESPP shares have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates. Because valuation model assumptions are subjective, in our opinion, existing valuation models, including the Black-Scholes-Merton model, may not provide reliable measures of the fair value of our share-based payment awards. There is not currently a generally accepted market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models. Although we estimate the fair value of employee share-based payment awards, the option-pricing model we use may not produce a value that is indicative of the fair value achieved in a willing buyer/willing seller market transaction.

The determination of fair value of share-based payment awards on the date of grant using the Black-Scholes-Merton model is affected by our stock price and the implied volatility on our traded options, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and our expected stock price volatility over the term of the awards. We use a blend of historical and implied volatility for the expected volatility assumption. We believe this not only takes into account past experience, but also expectations of how future volatility will differ from historical volatility. For purposes of estimating the fair value of stock options

granted to employees during the year ended December 31, 2009, we used a weighted average stock price volatility of 35%. If our stock price volatility assumptions were to increase 25% to 44%, the weighted average estimated fair value of stock options granted during the year ended December 31, 2009 would increase by $2.49 per share, or 20%.

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The expected term of stock options granted represents the period of time that they are expected to be outstanding. We use a midpoint scenario method, which assumes that all vested, outstanding options are settled halfway between the date of measurement and their expiration date. The calculation also leverages the history of actual exercises and post-vesting cancellations. For purposes of estimating the fair value of stock options granted to employees during the year ended December 31, 2009 we used a weighted average expected term of 4.33 years. If our expected term were to increase by one year to 5.33 years, the weighted average estimated fair value of stock options granted during the year ended December 31, 2009 would increase by $1.37 per share, or 11%.

Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We assess the forfeiture rate on a quarterly basis and revise the rate as necessary.

Marketable securities

The primary objectives of our marketable security investment portfolio are liquidity and safety of principal. Investments are made with the goal of achieving the highest rate of return consistent with these two objectives. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Marketable securities are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity under the caption Accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in Investment and interest income.

Realized gains and losses, and declines in value judged to be other-than-temporary on marketable securities, are included in Investment and interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in Investment and interest income.

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

We do not consider our investments in marketable securities with a current unrealized loss position to be other-than-temporarily impaired at December 31, 2009 because we do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at December 31, 2009 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of current portion, reflecting our current intent and ability to hold such investments to maturity. Our investments in municipal securities are classified as available-for-sale.

Valuation of inventories

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

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product demand, regulatory constraints or other market conditions are less favorable than those projected by management, additional inventory valuation reserves may be required.

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

For 2009, 2008 and 2007, total gross charges to our inventory reserves have not impacted gross margin, as a percentage of sales, by more than 0.6%. We believe that similar charges to estimated inventory reserves, and the related effect on gross margins, are reasonably likely in the future. Historically, changes to inventory valuation reserves in subsequent periods have not materially affected cost of product sales.

Valuation of goodwill and long-lived assets

Our business acquisitions typically result in the recording of goodwill and other intangible assets, and the recorded values of those assets may become impaired in the future. We also acquire intangible assets in other types of transactions. As of December 31, 2009, our goodwill and intangible assets (excluding capitalized software), net of accumulated amortization, were $122.2 million and $172.6 million, respectively. The determination of the value of such intangible assets requires management to make estimates and assumptions that affect our consolidated financial statements. For intangible assets purchased in a business combination, the estimated fair values of the assets received are used to establish their recorded values. Valuation techniques consistent with the market approach, income approach and/or cost approach are used to measure fair value. An estimate of fair value can be affected by many assumptions which require significant judgment. For example, the income approach generally requires assumptions related to the appropriate business model to be used to estimate cash flows, total addressable market, pricing and share forecasts, competition, technology obsolescence, future tax rates and discount rates. Our estimate of the fair value of certain assets, or our conclusion that the value of certain assets is not reliably estimable, may differ materially from determinations made by others who use different assumptions or utilize different business models. New information may arise in the future that affects our fair value estimates and could result in adjustments to our estimates in the future, which could have an adverse impact on our results of operations.

We assess the impairment of goodwill and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Impairment is reviewed at least annually, and occurs at the same time in the fourth quarter of each year, unless circumstances indicate that impairment has occurred before the fourth quarter of any given year. We completed our impairment test in the fourth quarter of 2009 and determined that the fair value of goodwill and long-lived assets exceeded the carrying value of those assets and therefore no impairment loss was necessary.

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

- significant underperformance relative to historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends;

significant declines in our stock price for a sustained period; and

decreased market capitalization relative to net book value.

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

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Our impairment analyses require management to make assumptions and to apply judgment to estimate future cash flows and asset fair values, including estimating the profitability of future business strategies. We have not made any material changes in our impairment assessment methodology during the past three fiscal years. We do not believe there is a reasonable likelihood that there will be a material change in the estimates or assumptions we use to calculate long-lived asset impairment losses. However, if actual results are not consistent with our estimates and assumptions used in estimating future cash flows and asset fair values, we may be exposed to losses that could be material.

Capitalized software costs

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

At December 31, 2009, capitalized software development costs related to products for use on our TIGRIS and PANTHER instruments totaled $12.1 million, net of accumulated amortization. We began amortizing the capitalized software costs related to our TIGRIS instrument on a straight-line basis over 120 months in May 2004, coinciding with the general release of TIGRIS instruments to our customers. Capitalized software development costs related to our PANTHER instrument will be amortized on a straight-line basis over 120 months upon commercialization of the instrument.

Equity investments in publicly and privately held companies

Effective January 1, 2008, we adopted guidance which defines fair value, expands disclosure requirements around fair value and specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

This hierarchy requires us to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. A financial instrument s categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Set forth below is a description of our valuation methodologies used for instruments measured at fair value, as well as the general classification of such instruments pursuant to the valuation hierarchy. Where appropriate, the description includes details of the valuation models, the key inputs to those models, as well as any significant assumptions.

Marketable securities

Our marketable securities include tax advantaged municipal securities, Federal Deposit Insurance Corporation, or FDIC, insured corporate bonds and money market funds. When available, we generally use quoted market prices to

determine fair value, and classify such items as Level 1. If quoted market prices are not available, prices are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals. We classify such items as Level 2. At December 31, 2009, we reported $437.1 million and $5.7 million of assets and liabilities, respectively, at fair value on a recurring basis as Level 2.

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Equity investment in public company

In April 2009, we made a $5.0 million preferred stock investment in DiagnoCure, a publicly held company traded on the Toronto Stock Exchange. Our equity investment was initially valued based on the transaction price under the cost method of accounting. The market value of the underlying common stock is the most observable value of the preferred stock, but because there is no active market for these preferred shares we have classified our equity investment in DiagnoCure as Level 2 in the fair value hierarchy. At December 31, 2009, we reported $5.0 million or 1.1% of assets measured at fair value on a non-recurring basis as related to equity investments in public companies.

Equity investments in private companies

The valuation of investments in non-public companies requires significant management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such assets. Our equity investments in private companies are initially valued based upon the transaction price under the cost method of accounting. Equity investments in non-public companies are classified as Level 3 in the fair value hierarchy. As of December 31, 2009, we reported $6.1 million, or 1.4% of assets measured at fair value on a non-recurring basis as Level 3 in the fair value hierarchy as related to equity investments in private companies.

In September 2009, we spun-off our industrial testing assets to Roka, a newly formed private company. In consideration for the contribution of assets, we received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis. Our investment in Roka totaled approximately $0.7 million as of December 31, 2009, and is included in Licenses, manufacturing access fees and other assets, net on our consolidated balance sheets.

In 2006, we invested in Qualigen, a private company. Our investment in Qualigen, which totaled approximately $5.4 million as of December 31, 2009, is also included in Licenses, manufacturing access fees and other assets, net on our consolidated balance sheets.

We record impairment charges when an investment has experienced a decline that is deemed to be other-than-temporary. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. Future adverse changes in market conditions or poor operating results of investees could result in losses or an inability to recover the carrying value of the investments, thereby possibly requiring impairment charges in the future. When assessing investments in private companies for an other-than-temporary decline in value, we consider many factors, including, but not limited to, the following: the share price from the investee s latest financing round; the performance of the investee in relation to its own operating targets and its business plan; the investee s revenue and cost trends; the investee s liquidity and cash position, including its cash burn rate; and market acceptance of the investee s products and services. From time to time, we may consider third party evaluations or valuation reports. We also consider new products and/or services that the investee may have forthcoming, any significant news specific to the investee, the investee s competitors and/or industry and the outlook of the overall industry in which the investee operates. In the event our judgments change as to other-than temporary declines in value, we may record an impairment loss, which could have an adverse effect on our results of operations.

Pending adoption of recent accounting pronouncements

EITF No. 08-1

In September 2009, the FASB ratified the final consensus reached by the Emerging Issues Task Force, or EITF, that revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be

effective for our fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We are currently in the process of evaluating early prospective adoption and determining the effects, if any, the adoption of the guidance will have on our consolidated financial statements.

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Results of Operations

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

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
Clinical diagnostics	$ 274.2	$ 222.9	$ 199.2	23%	12%
Blood screening	197.6	206.3	171.7	(4)%	20%
Research products and services	12.0			N/M	N/M
Total Product Sales	$ 483.8	$ 429.2	$ 370.9	13%	16%
As a percent of total revenues	97%	91%	92%		

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

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

Product sales increased by 13% in 2009 from 2008. The increase was primarily attributed to additional product sales as a result of our acquisitions of Tepnel and Prodesse and higher APTIMA assay sales, partially offset by a decrease in blood screening sales, primarily due to lower shipments and unfavorable exchange rate impacts.

Product sales increased 16% in 2008 from 2007. The increase was primarily attributed to higher blood screening and APTIMA assay sales, partially offset by lower PACE product sales as customers continued to convert to the more sensitive amplified APTIMA product line.

Clinical diagnostic product sales

Clinical diagnostic product sales, including assay, instrument, and ancillary sales, represented $274.2 million, or 57% of product sales in 2009, compared to $222.9 million, or 52% of product sales in 2008. The $51.3 million increase in clinical diagnostic product sales from 2008 to 2009 is primarily attributed to the addition of transplant diagnostic, genetic testing and infectious disease product sales resulting from our acquisitions of Tepnel and Prodesse, volume gains in our APTIMA product line as the result of PACE conversions, market share gains we attribute to the superior

clinical performance of our APTIMA assays and the availability of our fully automated TIGRIS instrument.

In general, the price of our amplified APTIMA test is twice that of our non-amplified PACE product, thus the conversion from PACE to APTIMA drives an overall increase in product sales even if underlying testing volumes remain the same.

During 2009, clinical diagnostic product sales were negatively affected as compared to 2008 by unfavorable estimated exchange rate impacts of $2.9 million, due to a stronger U.S. dollar.

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Clinical diagnostic product sales represented $222.9 million, or 52% of product sales in 2008, compared to $199.2 million, or 54% of product sales in 2007. This $23.7 million increase was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions, market share gains we attribute to the superior clinical performance of our APTIMA assays and the availability of our fully automated TIGRIS instrument. Overall APTIMA growth was partially offset by a decrease in PACE product sales as customers continued to convert to the more sensitive amplified APTIMA product line.

In 2008, we estimate that the growth of our clinical diagnostic product sales over 2007 was negatively affected by $0.3 million as the result of a stronger average U.S. dollar versus foreign currencies.

Blood screening product sales

Blood screening product sales, including assay, instrument, and ancillary sales, represented $197.6 million, or 41% of product sales in 2009, compared to $206.3 million, or 48% of product sales in 2008. The $8.7 million decrease in blood screening product sales from 2008 to 2009 is primarily attributed to test demand fluctuations from our partner Novartis and the unfavorable impact of foreign currency exchange rates. Blood screening shipments to Novartis were $18.4 million lower in 2009 than in 2008, primarily associated with lower U.S. shipments of the Procleix HIV-1/HCV assay as customers began to adopt the Procleix Ultrio assay, lower U.S. shipments of the Procleix Ultrio assay due to the post-marketing yield study which concluded at the end of 2008, and lower WNV test shipments. In addition to these factors, the decrease in blood screening product sales for 2009 was also caused by a one-time $2.6 million benefit related to our net share of revenue under our collaboration with Novartis recorded in the prior year.

During 2009, blood screening product sales were negatively affected as compared to the prior year period by unfavorable estimated exchange rate impacts of $6.1 million due to a stronger U.S. dollar.

Blood screening product sales represented $206.3 million or 48% of product sales in 2008, compared to $171.7 million, or 46% of product sales in 2007. This $34.6 million increase was principally attributed to the March 2007 approval and commercial pricing of our WNV assay for use on the TIGRIS instrument, as well as international expansion of Procleix Ultrio sales by Novartis. In 2008, U.S. blood donation volumes screened using the Procleix blood screening family of assays increased 4% over 2007 levels, while the related pricing increased 6%. International revenues increased as the Procleix Ultrio product further penetrated international markets. Included in the blood screening results for 2008 was a one-time $2.6 million benefit related to our net share of revenue under our collaboration with Novartis.

In 2008, we estimate that $5.0 million of the growth in blood screening product sales over 2007 was related to foreign currency gains associated with favorable exchange rates, primarily the weaker U.S. dollar versus the Euro, on revenues collected under our collaboration with Novartis.

Research products and services

As a result of our acquisition of Tepnel, we have a new category of product sales, which we refer to as Research products and services. These sales represent outsourcing services for pharmaceutical, biotechnology, and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies. These sales totaled $12.0 million in 2009.

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007

Collaborative Research Revenue	$ 7.9	$ 20.6	$ 16.6	(62)%	24%
As a percent of total revenues	2%	4%	4%		

We recognize collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned, in relative proportion to the performance required under the contracts, or as reimbursable costs are incurred related to those agreements. Non-refundable license fees are recognized over the related performance period or at the time that we have satisfied all performance obligations. Milestone payments

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are recognized as revenue upon the achievement of specified milestones. In addition, we record as collaborative research revenue shipments of blood screening products in the United States and other countries in which the products have not received regulatory approval. This is done because restrictions apply to these products prior to FDA marketing approval in the United States and similar approvals in foreign countries.

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

Collaborative research revenue decreased 62% in 2009 compared to 2008. The $12.7 million decrease was primarily due to a non-recurring $10.0 million milestone payment received from Novartis in the prior year and $4.5 million of revenue received from 3M Corporation, or 3M, related to our healthcare-associated infection collaboration which ended in June 2008. These decreases were partially offset by increased reimbursements from Novartis for shared development expenses, primarily attributable to development efforts for the PANTHER instrument in 2009.

Collaborative research revenue increased 24% in 2008 from 2007. The $4.0 million increase was primarily due to the $10.0 million milestone payment we received from Novartis based on the FDA s approval of our TIGRIS instrument system for use with our Ultrio assay, and an increase of $3.6 million from 3M for the development of rapid nucleic acid tests to detect certain dangerous healthcare-associated infections. This collaboration with 3M was discontinued in June 2008. These increases were partially offset by $3.6 million in lower funding revenues from the United States Army Medical Research and Material Command for the development of improved cancer diagnostic assays, as that contract expired in the fourth quarter of 2007, a $1.5 million decrease in funding revenues from Novartis for Ultrio assay development as that program neared completion, and a $3.9 million decrease in funding from 3M related to our food testing program that was discontinued in November 2007.

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

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
Royalty and License Revenue	$ 6.6	$ 22.9	$ 15.5	(71)%	48%
As a percent of total revenues	1%	5%	4%		

We recognize revenue for royalties due to us upon the manufacture, sale or use of our products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the applicable licensee. Non-refundable license fees are recognized over the related performance period or at the time that we have satisfied all performance obligations.

Royalty and license revenue decreased by 71% in 2009 as compared to 2008. The $16.3 million decrease was primarily due to the $16.4 million settlement payment we received from Siemens, as an assignee of Bayer, during the first quarter of 2008.

Our royalty and license revenue during 2008 and 2007 consisted primarily of settlement payments received from Siemens ($16.4 million in 2008 and $10.3 million in 2007). Siemens has now paid all amounts due to us under the settlement agreement, and thus these payments will not recur in future periods. The $7.4 million increase in

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royalty and license revenue during 2008 from 2007 was primarily the result of $6.1 million in higher amounts received from Siemens under the settlement agreement, $0.6 million in higher blood plasma royalties from Novartis, and $0.5 million in higher royalties from Becton Dickinson.

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

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
Cost of Product Sales	$ 152.4	$ 128.0	$ 119.6	19%	7%
Gross profit margin as a percent of product sales	69%	70%	68%		

Cost of product sales includes direct material, direct labor, and manufacturing overhead associated with the production of inventories. Other components of cost of product sales include royalties, warranty costs, instrument and software amortization and allowances for scrap. Cost of product sales excludes the amortization of acquisition-related intangibles.

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

Our blood screening manufacturing facility has operated, and we expect that it will continue to operate for the foreseeable future, below its potential capacity. A portion of this available capacity is utilized for R&D activities as new product offerings are developed for commercialization. As a result, certain operating costs of our blood screening manufacturing facility, together with other manufacturing costs for the production of pre-commercial development lot assays that are delivered under the terms of an IND application are classified as R&D expense prior to FDA approval.

Cost of product sales increased 19% in 2009 compared to 2008. The $24.4 million increase was primarily due to an additional $16.5 million in cost of product sales as a result of our acquisitions of Tepnel and Prodesse, an increase of $6.0 million attributed to manufacturing variances related to changes in production volumes, an increase of $4.6 million related to increased instrumentation volume, and an increase of $3.5 million related to increased APTIMA sales. These increased costs were partially offset by a decrease of $6.4 million attributed to lower blood screening assay shipments.

Our gross profit margin as a percentage of product sales decreased to 69% in 2009 from 70% in 2008. The decrease in gross profit margin as a percentage of product sales was principally attributed to lower overall gross margin percentages for the acquired Tepnel business, increased cost of product sales related to changes in production volumes and increased sales of lower margin instrumentation, which were partially offset by increased APTIMA sales.

Cost of product sales increased 7% in 2008 from 2007. Of this $8.4 million increase, $7.3 million was attributed to increased shipments of blood screening products, $6.2 million was attributed to increased APTIMA sales, $1.8 million

was attributed to increased amortization of capitalized intangible assets, $1.5 million was attributed to higher instrument sales and instrument related costs, and $0.7 million was attributed to increased viral sales. These 2008 increases were partially offset by a $9.3 million benefit compared to 2007 as a result of higher production volumes.

Our gross profit margin as a percentage of product sales increased to 70% in 2008 from 68% in 2007. The increase in gross profit margin percentage was principally attributed to increased sales of blood screening assays by Novartis and increased APTIMA sales, which have higher margins, and favorable changes in production volumes,

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partially offset by increased instrument sales, which have lower margins, and instrument related costs and increased amortization of capitalized intangible assets.

Cost of sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales is also affected by manufacturing efficiencies, allowances for scrap or expired materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

A portion of our blood screening revenues is attributable to sales of TIGRIS instruments to Novartis, which totaled $15.9 million, $12.4 million and $9.4 million during 2009, 2008, and 2007, respectively. Under our collaboration agreement with Novartis, we sell TIGRIS instruments to them at prices that approximate cost and share in profits of end-user sales in the United States. These instrument sales, therefore, negatively impact our gross margin percentage in the periods when they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
Acquisition-related Intangible Amortization	$ 4.1	$	$	N/M	N/M
As a percent of total revenues	1%	0%	0%		

Amortization expense related to our acquired intangibles was $4.1 million in 2009. Intangible assets are amortized using the straight-line method over their estimated useful lives, which range from 10 to 20 years. For details on the intangible assets acquired as part of our acquisitions of Tepnel and Prodesse, please refer to Note 2 Business combinations, of the Notes to the Consolidated Financial Statements included in Item 8 of Part II of this report.

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
Research and Development	$ 106.0	$ 101.1	$ 97.1	5%	4%
As a percent of total revenues	21%	21%	24%		

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

We expect to incur additional costs associated with our research and development activities. The additional costs include development and validation activities for our HPV, PCA3 and Trichomonas assays, development of our PANTHER instrument, assay integration activities for PANTHER, development and validation of assays for blood screening and ongoing research and early stage development activities. Although total R&D expenditures may increase over time, we expect that our R&D expenses as a percentage of total revenues will decline in future years.

R&D expenses increased 5% in 2009 from 2008. The $4.9 million increase was primarily due to the addition of Tepnel s R&D expenses which totaled $3.1 million in 2009, as well as increased spending of $5.9 million in 2009 for clinical evaluations primarily associated with our HPV clinical trial, partially offset by a $4.4 million decrease in amortization due mostly to an impairment charge recorded in the second quarter of 2008 associated with our license agreement with Corixa Corporation, or Corixa.

R&D expenses increased 4% in 2008 from 2007. The $3.9 million increase was primarily due to a $4.8 million increase in clinical evaluations and outside services associated with our Procleix Ultrio yield studies, for which we received blood screening approval in August 2008, HPV trials which began in March 2008, as well as our license

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agreement with Xceed, $2.7 million in higher amortization charges due in part to an impairment charge associated with our Corixa license agreement, and an increase of $1.3 million in salaries and personnel-related expenses. These increases were partially offset by a $3.0 million decrease in development lot activity, primarily related to timing of our HPV diagnostic product, and an $0.8 million decrease in professional fees for consulting services.

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
Marketing and Sales	$ 53.9	$ 45.9	$ 39.9	17%	15%
As a percent of total revenues	11%	10%	10%		

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

Marketing and sales expenses increased 17% in 2009 from 2008. The $8.0 million increase is primarily attributed to the addition of marketing and sales expenses as a result of our acquisition of Tepnel, which totaled $5.3 million, in 2009, as well as a $2.4 million increase in salaries and personnel-related expenses due to our continued investment in international expansion efforts, primarily in Western Europe, and the related promotion and sale of our more recently launched CE-marked PCA3 and HPV products.

Marketing and sales expenses increased 15% in 2008 from 2007. The $6.0 million increase was primarily due to a $3.3 million increase in salaries and personnel-related expenses resulting from the hiring of additional employees, a $1.3 million increase in spending for marketing studies and promotional activities, and a $0.6 million increase in travel expenses, all of which were a result of our increased international market development efforts and PCA3 and HPV market development.

	Years Ended December 31,			% Change	
(Dollars in millions)	2009	2008	2007	2009/2008	2008/2007
General and Administrative	$ 61.8	$ 52.3	$ 47.0	18%	11%
As a percent of total revenues	12%	11%	12%		

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

G&A expenses increased 18% in 2009 from 2008. The $9.5 million increase is primarily attributed to the addition of Tepnel s G&A expenses, which totaled $7.5 million in 2009, as well as business development costs associated with the Tepnel and Prodesse acquisitions and the spin-off of our industrial testing assets to Roka, which totaled $6.3 million in 2009. These increases were offset by a $2.7 million decrease in legal fees due to the completion of the Digene arbitration.

G&A expenses increased 11% in 2008 from 2007. The $5.3 million increase was primarily the result of a $3.6 million increase in professional fees, primarily legal and business development expenses, a $2.1 million increase in salaries and personnel-related expenses and a $1.3 million increase in commercial and investment banking charges, primarily attributable to our counterbid to acquire Innogenetics in 2008. These increases were

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partially offset by a $1.2 million decrease in relocation expenses associated with senior level personnel hired in 2007.

(Dollars in millions)	Years Ended December 31, 2009	2008	2007	% Change 2009/2008	2008/2007
Investment and interest income	$ 21.6	$ 16.8	$ 12.8	29%	31%
Interest expense	(1.9)			N/M	N/M
Other income / (expense)		(1.3)	(0.5)	N/M	160%
Total other income, net	$ 19.7	$ 15.5	$ 12.3	27%	26%

The increase in investment and interest income in 2009 from 2008 is primarily attributed to $10.5 million in net realized gains on sales of marketable securities, partially offset by decreased interest income due to lower investment balances in the current year as a result of our recent acquisitions. In 2009, we recorded $1.9 million of interest expense attributable to borrowings under our credit facility with Bank of America. The net increase in other income in 2009 from 2008 was primarily attributable to a $1.6 million impairment charge on our investment in Qualigen recorded in the third quarter of 2008, as well as favorable exchange rate impacts in 2009.

The $4.0 million increase in investment and interest income in 2008 from 2007 was primarily a result of higher average balances of our marketable securities, which on average increased by $158.1 million, or 54%. Included in the $0.8 million net increase in other expense was a $1.6 million gain resulting from the sale of our equity interest in Molecular Profiling Institute, Inc., which was offset by an impairment charge of $1.6 million related to our investment in Qualigen. The remaining $0.8 million was attributable to foreign currency exchange losses.

(Dollars in millions)	Years Ended December 31, 2009	2008	2007	% Change 2009/2008	2008/2007
Income Tax Expense	$ 48.0	$ 53.9	$ 25.5	(11)%	111%
As a percentage of income before tax	34%	34%	23%		

Our effective tax rate in 2009 was consistent with 2008 primarily due to the offset of greater benefits from research tax credits and the negative impact of lower tax advantaged interest income.

Income tax expense, as a percentage of pre-tax income, increased in 2008 from 2007. This increase was principally attributed to the 2007 completion of federal and state audits of our tax returns through 2004, which resulted in $11.1 million of net tax benefits for reserves in excess of audit adjustments.

Liquidity and capital resources

	2009	2008	2007	Amount Change From 2008 to 2009
	(In thousands)			

As of December 31:				
Cash, cash equivalents and current marketable securities	$ 485,606	$ 431,398	$ 395,417	$ 54,208
Working capital	331,182	506,457	480,321	(175,275)
Current ratio	2:1	12:1	13:1	

Our working capital at December 31, 2009 decreased $175.3 million from December 31, 2008 primarily due to the current liability created by our credit facility with Bank of America, which was partially offset by borrowings under the credit facility. In April 2009, we used approximately $137.1 million in borrowings under the credit facility

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to acquire Tepnel. Days sales outstanding, or DSO, for the year ended December 31, 2009 was 31 days compared to the prior year at 28 days.

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

Our marketable securities include tax advantaged municipal securities and Federal Deposit Insurance Corporation, or FDIC, insured corporate bonds with a minimum Moody s credit rating of A3 or a Standard & Poor s credit rating of A-. As of December 31, 2009, we did not hold auction rate securities and have never held any such securities. Our investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At December 31, 2009, our portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody s.

	2009	2008	2007	Amount Change From 2008 to 2009
		(In thousands)		
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	$ 145,031	$ 178,253	$ 109,584	$ (33,222)
Investing activities	(198,378)	(139,888)	(183,424)	(58,490)
Financing activities	74,815	(53,534)	61,812	128,349
Purchases of property, plant and equipment (included in investing activities above)	(32,364)	(39,348)	(23,096)	6,984

Our primary source of liquidity has been cash from operations, which includes the collection of accounts and other receivables related to product sales, collaborative research agreements, and royalty and license fees. Additionally, our liquidity was enhanced in 2009 by our recently established credit facility with Bank of America, described in Note 9 Short-term borrowings, of the Notes to the Consolidated Financial Statements included in Item 8 of Part II of this report. Our primary short-term cash needs, which are subject to change, include continued R&D spending to support new products, costs related to commercialization of products and purchases of instrument systems, primarily TIGRIS, for placement with our customers. In addition, we may use cash for strategic purchases which may include the acquisition of businesses and/or technologies complementary to our business. Certain R&D costs may be funded under collaboration agreements with our collaboration partners.

Operating activities provided net cash of $145.0 million in 2009, primarily from net income of $91.8 million, net non-cash charges of $60.3 million, partially offset by a decrease in cash from operating assets and liabilities of $7.0 million. Non-cash charges primarily consisted of depreciation of $27.6 million, amortization of intangibles of $12.8 million and stock based compensation expense of $23.4 million.

Net cash used in investing activities for 2009 was $198.4 million. Net cash paid for the acquisitions of Tepnel and Prodesse totaled $183.7 million, $32.4 million was used for purchases of property, plant and equipment, and $5.0 million was used to purchase preferred stock in DiagnoCure. These uses of cash were offset by $19.6 million in net proceeds from the sale of marketable securities and $6.4 million in net proceeds from the divestiture of our BioKits food safety testing business.

Net cash provided by financing activities in 2009 was $74.8 million, primarily driven by $240.0 million in borrowings under our credit facility, partially offset by $174.8 million used to repurchase and retire approximately 4,283,000 shares of our common stock under our stock repurchase program.

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

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future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to covenants restricting our operations.

Contractual obligations and commercial commitments

Our contractual obligations due for purchase commitments, collaborative agreements and minimum royalties as of December 31, 2009 were as follows (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Material purchase commitments[1]	$ 54,495	$ 44,623	$ 4,426	$ 3,455	$ 1,991
Operating leases[2]	7,320	1,690	3,097	2,281	252
Collaborative commitments[3]	5,625	1,527	1,951	750	1,397
Minimum royalty commitments[4]	16,527	1,282	3,170	3,840	8,235
Deferred employee compensation[5]	4,056	939	1,211	1,110	796
Capital leases[6]	667	173	464	30	
Contingent consideration[7]	17,994	8,396	9,598		
Total[8]	$ 106,684	$ 58,630	$ 23,917	$ 11,466	$ 12,671

(1) Amounts represent our minimum purchase commitments from key vendors for the TIGRIS, PANTHER, Luminex and Cepheid instruments, as well as raw materials used in manufacturing. Of the $54.5 million total, $30.9 million is expected to be used to purchase TIGRIS instruments, of which we anticipate that approximately $16.0 million of instruments will be sold to Novartis. Not included in the $54.5 million is $6.6 million expected to be used to purchase pre-production and production instruments, and associated tooling, pursuant to our development agreement with Stratec for the PANTHER instrument, as well as potential minimum purchase commitments under our supply agreement with Stratec. Our obligations under the supply agreement are contingent on successful completion of all activities under the development agreement with Stratec.

(2) Reflects obligations for facilities and vehicles under operating leases in place as of December 31, 2009. Future minimum lease payments are included in the table above.

(3) In addition to the minimum payments due under our collaborative agreements, we may be required to pay up to $11.2 million in milestone payments, plus royalties on net sales of any products using specified technology. We may also be required to pay up to $3.4 million in future development costs in the form of milestone payments.

(4) Amounts represent our minimum royalties due on the net sales of products incorporating licensed technology and subject to a minimum annual royalty payment. During the year ended December 31, 2009, we recorded $9.2 million in royalty costs related to our various license agreements.

(5) We have liabilities for deferred employee compensation which totaled $5.7 million at December 31, 2009. Under our deferred compensation plan, participants may elect in-service distributions on specified future dates, or a distribution upon retirement. Of the $5.7 million, $2.2 million is payable upon employee retirement and as such was not included in the table above as we cannot reasonably predict when a retirement event may occur. Total

liabilities for deferred employee compensation are partially offset by deferred compensation assets, which totaled $5.7 million at December 31, 2009.

(6) Reflects obligations on capital leases in place as of December 31, 2009. Interest amounts were not material, therefore, capital lease obligations are shown net of interest expense in the table above.

(7) Represents the aggregate fair value of the payments we may be obligated to make to former Prodesse securityholders. This amount is reflected in our balance sheet under the captions Other accrued expenses and Other long-term liabilities.

(8) Does not include amounts relating to our obligations under our collaboration with Novartis, pursuant to which both parties have obligations to each other. We are obligated to manufacture and supply blood screening assays

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

Liabilities associated with uncertain tax positions, currently estimated at $7.5 million (including interest), are not included in the table above as we cannot reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

As of December 31, 2009, the total principal amount outstanding under our revolving credit facility with Bank of America was $240.0 million. The term of this credit facility is due to expire in February 2011. For additional information regarding the terms of this credit facility, please see the description included in Note 9 Short-term borrowings, of the Notes to the Consolidated Financial Statements included in Item 8 of Part II of this report.

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

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

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our investment portfolio and the amount of interest payable on our senior secured revolving credit facility with Bank of America. As of December 31, 2009, the total principal amount outstanding under the revolving credit facility was $240.0 million. At our option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America s prime rate and (iii) LIBOR plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by us. We do not believe that we are exposed to significant interest rate risk with respect to our credit facility based on our option to select the rate at which interest accrues under the credit facility, the short-term nature of the borrowings and our ability to pay off the outstanding balance in a timely manner if the applicable interest rate under the credit facility increases above the current interest rate yields on our investment portfolio. A 100 basis point increase or decrease in interest rates would increase or decrease our interest expense by approximately $2.4 million on an annual basis. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in investment grade securities with an average portfolio maturity of no more than three years. A 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately $7.0 million on an annual basis. While changes in interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our consolidated statements of income until the investment is sold or if a reduction in fair value is determined to be other-than-temporary.

Foreign Currency Exchange Risk

Although the majority of our revenue is realized in United States dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. We translate the financial statements of our non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates in intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders equity under the caption

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Accumulated other comprehensive income. These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Under our collaboration agreement with Novartis, a growing portion of blood screening product sales is from western European countries. As a result, our international blood screening product sales are affected by changes in the foreign currency exchange rates of those countries where Novartis business is conducted in Euros or other local currencies. Based on international blood screening product sales during 2009, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.7 million annually. Similarly, a 10% movement of currency exchange rates would result in a diagnostic product sales increase or decrease of approximately $2.9 million annually. Our exposure for both blood screening and diagnostic product sales is primarily in the United States dollar versus the Euro, British pound, Australian dollar, and Canadian dollar.

Our total payables denominated in foreign currencies as of December 31, 2009 were not material. Our receivables by currency as of December 31, 2009 reflected in U.S. dollar equivalents were as follows (in thousands):

U.S. dollars	$ 44,406
British pounds	5,632
Euro	3,796
Canadian dollars	1,595
Czech koruna	209
Danish krone	161
Swiss franc	22
Total gross trade accounts receivable	$ 55,821

In order to reduce the effect of foreign currency fluctuations, we periodically utilize foreign currency forward exchange contracts, or forward contracts, to hedge certain foreign currency transaction exposures. Specifically, we enter into forward contracts with a maturity of approximately 30 days to hedge against the foreign exchange exposure created by certain balances that are denominated in a currency other than the principal reporting currency of the entity recording the transaction. The forward contracts do not qualify for hedge accounting and, accordingly, all of these instruments are marked to market at each balance sheet date by a charge to earnings. The gains and losses on the forward contracts are meant to mitigate the gains and losses on these outstanding foreign currency transactions. We believe that these forward contracts do not subject us to undue risk due to foreign exchange movements because gains and losses on these contracts are generally offset by losses and gains on the underlying assets and liabilities. We do not use derivatives for trading or speculative purposes. Although the effect of currency fluctuations on our financial results has generally been immaterial in the past, we recorded a realized loss of $0.9 million for the twelve months ended December 31, 2009.

We did not enter into any foreign currency forward contracts during the three months ended December 31, 2009.

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

Our consolidated financial statements and the Reports of Ernst & Young LLP, our Independent Registered Public Accounting Firm, are included in this Annual Report on Form 10-K on pages F-1 through F-39.

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

None.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our current and periodic reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely

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decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of 2009.

Changes in Internal Control Over Financial Reporting

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

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2009 based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2009.

On October 22, 2009, we completed the acquisition of Prodesse. The 2009 financial statements of Prodesse constituted less than 10% of total assets as of December 31, 2009 and less than 10% of revenues and net income for the year then ended. We have not completed our evaluation of the design and operation of internal control over financial reporting of this consolidated subsidiary as of December 31, 2009 due to the timing of the completion of the transaction and as allowed by Securities and Exchange Commission rules. We will complete such evaluation in fiscal year 2010.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2009. This report, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2009, is included elsewhere herein.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Gen-Probe Incorporated:

We have audited Gen-Probe Incorporated s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Gen-Probe Incorporated s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

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

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

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

As indicated in the accompanying Management s Report on Internal Control Over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Prodesse, Inc., which is included in the 2009 consolidated financial statements of Gen-Probe Incorporated and constituted less than 10% of total assets as of December 31, 2009 and less than 10% of revenues and net income for the year then ended. Our audit of internal control over financial reporting of Gen-Probe Incorporated also did not include an evaluation of the internal control over financial reporting of Prodesse, Inc.

In our opinion, Gen-Probe Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2009 and 2008, and the related

consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2009 and our report dated February 25, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 25, 2010

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Item 9B. ***Other Information***

None.

PART III

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

The information required by this Item is incorporated in this report by reference from the information under the captions Information Regarding the Board of Directors and Corporate Governance, Executives and Section 16(a) Beneficial Ownership Reporting Compliance contained in the Proxy Statement to be filed in connection with our 2010 Annual Meeting of Stockholders, or the Proxy Statement.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Ethics. The Code of Ethics is available on our website at http://www.gen-probe.com. Stockholders may request a free copy of the Code of Ethics from:

Gen-Probe Incorporated
Attention: Investor Relations
10210 Genetic Center Drive
San Diego, CA 92121-4362
(858) 410-8000
http://www.gen-probe.com

Item 11. ***Executive Compensation***

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

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

The information required by this Item is incorporated in this report by reference from the information under the captions Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information contained in the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this Item is incorporated in this report by reference from the information under the captions Certain Related Person Transactions, Related Person Transaction Policy and Procedures and Information Regarding the Board of Directors and Corporate Governance contained in the Proxy Statement.

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

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

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PART IV

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

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

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2009 and 2008

Consolidated Statements of Income for each of the three years in the period ended December 31, 2009

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2009

Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2009

Notes to Consolidated Financial Statements

2. Schedule II Valuation and Qualifying Accounts and Reserves for each of the three years in the period ended December 31, 2009

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

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

(b) *Exhibits.* See the Exhibit Index and Exhibits filed as part of this report.

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SIGNATURES

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

GEN-PROBE INCORPORATED

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

Date: February 25, 2010

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

Signature	Title	Date
/s/ Carl W. Hull Carl W. Hull	President, Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2010
/s/ Herm Rosenman Herm Rosenman	Senior Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2010
/s/ Henry L. Nordhoff Henry L. Nordhoff	Chairman	February 25, 2010
/s/ John W. Brown John W. Brown	Director	February 25, 2010
/s/ Armin M. Kessler Armin M. Kessler	Director	February 25, 2010
/s/ John C. Martin, John C. Martin, Ph.D.	Director	February 25, 2010
/s/ Phillip M. Schneider Phillip M. Schneider	Director	February 25, 2010

/s/ Lucy Shapiro Lucy Shapiro, Ph.D.	Director	February 25, 2010
/s/ Abraham D. Sofaer Abraham D. Sofaer	Director	February 25, 2010

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GEN-PROBE INCORPORATED

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Gen-Probe Incorporated:

We have audited the accompanying consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2009 and 2008, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gen-Probe Incorporated at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Gen-Probe Incorporated s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 25, 2010

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GEN-PROBE INCORPORATED

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents, including restricted cash of $17 and $0 at December 31, 2009 and 2008, respectively	$ 82,616	$ 60,122
Marketable securities	402,990	371,276
Trade accounts receivable, net of allowance for doubtful accounts of $516 and $700 at December 31, 2009 and 2008, respectively	55,305	33,397
Accounts receivable other	4,707	2,900
Inventories	61,071	54,406
Deferred income tax short term	16,082	7,269
Prepaid income tax	7,317	2,306
Prepaid expenses	14,747	15,094
Other current assets	4,708	6,135
Total current assets	649,543	552,905
Marketable securities, net of current portion	15,472	73,780
Property, plant and equipment, net	157,437	141,922
Capitalized software, net	12,560	13,409
Goodwill	122,247	18,621
Deferred income tax, net of current portion	8,692	12,286
Purchased intangibles, net	108,015	298
License, manufacturing access fees and other assets, net	64,601	56,310
Total assets	$ 1,138,567	$ 869,531
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 26,750	$ 16,050
Accrued salaries and employee benefits	27,093	25,093
Other accrued expenses	18,027	4,027
Short-term borrowings	240,841	
Deferred income tax	2,123	
Deferred revenue	3,527	1,278
Total current liabilities	318,361	46,448
Non-current income tax payable	5,958	4,773
Deferred income tax, net of current portion	31,912	55
Deferred revenue, net of current portion	1,978	2,333
Other long-term liabilities	13,183	2,162

Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized, 49,143,798 and 52,920,971 shares issued and outstanding at December 31, 2009 and 2008, respectively	5	5
Additional paid-in capital	242,615	382,544
Accumulated other comprehensive income	4,616	3,055
Retained earnings	519,939	428,156
Total stockholders equity	767,175	813,760
Total liabilities and stockholders equity	$ 1,138,567	$ 869,531

See accompanying notes to consolidated financial statements

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share data)

	Years Ended December 31,		
	2009	2008	2007
Revenues:			
Product sales	$ 483,759	$ 429,220	$ 370,877
Collaborative research revenue	7,911	20,581	16,619
Royalty and license revenue	6,632	22,894	15,518
Total revenues	498,302	472,695	403,014
Operating expenses:			
Cost of product sales (excluding acquisition-related intangible amortization)	152,393	128,029	119,641
Acquisition-related intangible amortization	4,144		
Research and development	105,970	101,099	97,144
Marketing and sales	53,853	45,850	39,928
General and administrative	61,828	52,322	47,007
Total operating expenses	378,188	327,300	303,720
Income from operations	120,114	145,395	99,294
Other income/(expense):			
Investment and interest income	21,603	16,801	12,772
Interest expense	(1,857)		
Other income/(expense)	(58)	(1,333)	(469)
Total other income, net	19,688	15,468	12,303
Income before income tax	139,802	160,863	111,597
Income tax expense	48,019	53,909	25,457
Net income	$ 91,783	$ 106,954	$ 86,140
Net income per share:			
Basic	$ 1.82	$ 1.98	$ 1.62
Diluted	$ 1.79	$ 1.95	$ 1.58
Weighted average shares outstanding:			
Basic	50,356	53,740	52,860
Diluted	50,965	54,785	54,355

See accompanying notes to consolidated financial statements

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2009	2008	2007
Operating activities			
Net income	$ 91,783	$ 106,954	$ 86,140
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	40,382	34,715	34,159
Amortization of premiums on investments, net of accretion of discounts	5,868	6,908	4,576
Stock-based compensation charges	23,420	20,663	19,651
Stock-based compensation income tax benefits	3,343	3,276	2,596
Excess tax benefit from employee stock-based compensation	(2,005)	(2,493)	(14,606)
Deferred revenue	812	(3,831)	2,855
Deferred income tax	(5,786)	(2,788)	(7,621)
Gain on sale of investment in MPI		(1,600)	
Gain on sale of food safety business	(291)		
Impairment of intangible assets		5,086	
Loss on disposal of property and equipment	221	55	703
Changes in assets and liabilities:			
Trade and other accounts receivable	(11,303)	7,421	(16,180)
Inventories	2,315	(5,367)	3,588
Prepaid expenses	1,218	2,325	(6,141)
Other current assets	1,912	(1,260)	(2,307)
Other long-term assets	(4,123)	(173)	(1,131)
Accounts payable	3,500	4,377	(1,818)
Accrued salaries and employee benefits	(676)	4,125	4,273
Other accrued expenses	(806)	101	679
Income tax payable	(5,714)	(499)	(397)
Other long-term liabilities	961	258	565
Net cash provided by operating activities	145,031	178,253	109,584
Investing activities			
Proceeds from sales and maturities of marketable securities	438,601	105,994	140,988
Purchases of marketable securities	(419,019)	(198,691)	(298,824)
Purchases of property, plant and equipment	(32,364)	(39,348)	(23,096)
Capitalization of software development costs	(1,290)		
Purchases of intangible assets, including license and manufacturing access fees	(7,341)	(11,970)	(2,213)
Net cash paid for business combinations	(183,725)		
Proceeds from sale of food safety business	6,357		

Proceeds from sale of investment in MPI		4,100	
Other assets	403	27	(279)
Net cash used in investing activities	(198,378)	(139,888)	(183,424)
Financing activities			
Excess tax benefit from stock-based compensation	2,005	2,493	14,606
Repurchase and retirement of restricted stock for payment of taxes	(1,716)	(1,529)	(1,474)
Repurchase and retirement of common stock	(174,847)	(74,970)	
Proceeds from issuance of common stock and ESPP	10,923	20,472	48,680
Borrowings, net	238,450		
Net cash provided by (used in) financing activities	74,815	(53,534)	61,812
Effect of exchange rate changes on cash and cash equivalents	1,026	(672)	86
Net increase (decrease) in cash and cash equivalents	22,494	(15,841)	(11,942)
Cash and cash equivalents at the beginning of year	60,122	75,963	87,905
Cash and cash equivalents at the end of year	$ 82,616	$ 60,122	$ 75,963
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 1,955	$ 3	$
Cash paid for taxes	$ 54,933	$ 54,783	$ 32,208

See accompanying notes to consolidated financial statements

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(In thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders Equity
Balance at December 31, 2006	52,234	$ 5	$ 334,184	$ (5)	$ 236,024	$ 570,208
Cumulative effect adjustment upon the adoption of FIN No. 48					(962)	(962)
Common stock issued from exercise of stock options	1,539		45,129			45,129
Purchase of common stock through employee stock purchase plan	74		3,550			3,550
Purchase of common stock by board members	2		128			128
Issuance of restricted stock awards, net of cancellations	71					
Issuance of deferred issuance restricted stock awards	20					
Repurchase and retirement of restricted stock for payment of taxes	(24)		(1,474)			(1,474)
Stock-based compensation charges			19,455			19,455
Stock-based compensation income tax benefits			14,257			14,257
Comprehensive income:						
Net income					86,140	86,140
Foreign currency translation adjustment				(566)		(566)
Change in net unrealized gain on marketable securities net of income tax benefits of $1,196				2,345		2,345
Reclassification of net realized loss on marketable securities, net of income tax benefits of $91				(170)		(170)
Comprehensive income						87,749

Balance at December 31, 2007	53,916	$ 5	$ 415,229	$ 1,604	$ 321,202	$ 738,040
Common stock issued from exercise of stock options	525		16,771			16,771
Repurchase and retirement of common stock	(1,705)		(74,970)			(74,970)
Purchase of common stock through employee stock purchase plan	98		3,701			3,701
Purchase of common stock by board members	3		148			148
Issuance of restricted stock awards, net of cancellations	91					
Issuance of deferred issuance restricted stock awards	20					
Repurchase and retirement of restricted stock for payment of taxes	(27)		(1,529)			(1,529)
Stock-based compensation charges			20,701			20,701
Stock-based compensation income tax benefits			2,493			2,493
Comprehensive income:						
Net income					106,954	106,954
Foreign currency translation adjustment				(284)		(284)
Change in net unrealized gain on marketable securities net of income tax benefits of $935				1,079		1,079
Reclassification of net realized gain on marketable securities, net of income tax expense of $353				656		656
Comprehensive income						108,405
Balance at December 31, 2008	52,921	$ 5	$ 382,544	$ 3,055	$ 428,156	$ 813,760
Common stock issued from exercise of stock options	374		6,828			6,828
Repurchase and retirement of common stock	(4,283)		(174,847)			(174,847)
Purchase of common stock through employee stock purchase plan	112		4,095			4,095
Purchase of common stock by board members	4		176			176
Issuance of restricted stock awards, net of cancellations	24					

Issuance of deferred issuance restricted stock awards	34					
Repurchase and retirement of restricted stock for payment of taxes	(42)		(1,716)			(1,716)
Stock-based compensation charges			23,530			23,530
Stock-based compensation income tax benefits			2,005			2,005
Comprehensive income:						
Net income					91,783	91,783
Foreign currency translation adjustment				2,705		2,705
Change in net unrealized loss on marketable securities net of income tax benefits of $616				(7,981)		(7,981)
Reclassification of net realized gain on marketable securities, net of income tax expense of $3,681				6,837		6,837
Comprehensive income						93,343
Balance at December 31, 2009	49,144	$ 5	$ 242,615	$ 4,616	$ 519,939	$ 767,175

See accompanying notes to consolidated financial statements

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Organization and summary of significant accounting policies

Organization and basis of presentation

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

In accordance with the Subsequent Events Topic of the Financial Accounting Standards Board (FASB) Accounting Standards Codification, the Company evaluated subsequent events after the balance sheet date of December 31, 2009 and through the date and time its consolidated financial statements were issued on February 25, 2010.

Certain prior year amounts have been reclassified to conform to the current year presentation. In the quarter ended March 31, 2009, the Company began reporting investments in an unrealized loss position deemed to be temporary that have a contractual maturity of greater than 12 months as non-current marketable securities. This resulted in the reclassification of $73.8 million of marketable securities as non-current under the caption Marketable securities, net of current portion at December 31, 2008.

Principles of consolidation

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

In April 2009, the Company acquired Tepnel Life Sciences plc (Tepnel), a United Kingdom (UK) based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd. Tepnel s transplant diagnostics and genetic testing businesses are included in the Company s diagnostic operations beginning in April 2009. While Tepnel s research products and services business represents a new area of business for the Company, the activities of the research products and services business were immaterial to the Company s overall operations for 2009.

In October 2009, the Company acquired Prodesse, Inc. (Prodesse), now known as Gen-Probe Prodesse, Inc., a privately held Wisconsin corporation. Prodesse develops molecular diagnostic products for a variety of infectious disease applications.

Use of estimates

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

licenses and manufacturing access fees. Actual results could differ from those estimates.

Foreign currencies

The Company translates the financial statements of its non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates on intercompany receivables and payables of a long-term investment nature are recorded as a separate component of

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

stockholders equity under the caption Accumulated other comprehensive income. These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Segment information

The Company currently operates in one business segment, the development, manufacturing, marketing, sales and support of molecular diagnostic products primarily to diagnose human diseases and screen donated human blood. Although the Company s products comprise distinct product lines to serve different end markets within molecular diagnostics, the Company does not operate its business in multiple business units or operating segments. The Company is managed by a single functionally based management team that manages all aspects of the Company s business and reports directly to the Chief Executive Officer. For all periods presented, the Company operated in a single business segment. Revenue by geographic location is presented in Note 15.

Revenue recognition

The Company records shipments of its clinical diagnostic products as product sales when the product is shipped and title and risk of loss has passed and when collection of the resulting receivable is reasonably assured.

The Company manufactures blood screening products according to demand specifications of its collaboration partner, Novartis Vaccines and Diagnostics, Inc. (Novartis). Upon shipment to Novartis, the Company recognizes blood screening product sales at an agreed upon transfer price and records the related cost of products sold. Based on the terms of its collaboration agreement with Novartis, the Company s ultimate share of the net revenue from sales to the end user is not known until reported by Novartis. The Company then adjusts blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting the Company s ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized. The Company amended its agreement with Novartis effective as of January 1, 2009 to decrease the time period between product sales and net payment of its share of blood screening assay revenue from 45 days to 30 days.

Generally, the Company provides its instrumentation to reference laboratories, public health institutions and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, the Company recovers the cost of providing the instrumentation in the amount it charges for its diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

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

The Company records shipments of its blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue. This is done because price restrictions apply to these products prior to FDA marketing approval in the United States and similar approvals in foreign countries. Upon shipment of FDA-approved and labeled products following regulatory approval, the Company classifies sales of these products as product sales in its consolidated financial statements.

The Company records revenue on its research product sales upon delivery of the goods and on its research services in the period during which the related costs are incurred, or services are provided. These revenues consist of

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

outsourcing services for pharmaceutical, biotechnology, and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

The Company analyzes each element of its collaborative arrangements to determine the appropriate revenue recognition. The Company recognizes revenue on up-front payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. According to FASB guidance, revenue arrangements with multiple deliverables are divided into separate units of accounting if (i) the delivered item has stand-alone value, (ii) the vendor has objective and reliable evidence of fair value of the undelivered item(s), and (iii) the customer has a general right of return relative to the delivered item(s) and delivery or performance of the undelivered item is probable and substantially within the vendor s control. All of these criteria must be met in order for a delivered item to be accounted for as a separate unit.

The Company recognizes collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the applicable contracts. Non-refundable license fees are recognized over the related performance period or at the time that the Company has satisfied all performance obligations. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) the Company has earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement, (iii) the fees are non-refundable, and (iv) performance obligations after the milestone achievement will continue to be funded by the collaborator at a level comparable to the level before the milestone achievement. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheets.

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

Cost of product sales

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

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

Research and development, Marketing and sales, and General and administrative, based on the nature of the costs.

Stock-based compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period on a straight-line basis. As of December 31, 2009, there were no outstanding equity awards with market or performance conditions. Stock-

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

based compensation expense is recognized based on the value of share-based payment awards that are ultimately expected to vest, which coincides with the award holder s requisite service period. Certain of these costs are capitalized into inventory on the Company s balance sheet, and are recognized as an expense when the related products are sold.

Shipping and handling expenses

Shipping and handling expenses included in cost of product sales totaled approximately $7.3 million, $6.7 million, and $5.6 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Contingencies

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

Income tax

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

The Company s income tax returns are based on calculations and assumptions that are subject to examination by various tax authorities. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of these examinations and any future examinations in determining the adequacy of its provision for income taxes. As part of its assessment of potential adjustments to its tax returns, the Company increases its current tax liability to the extent an adjustment would result in a cash tax payment or decreases its deferred tax assets to the extent an adjustment would not result in a cash tax payment. The Company reviews, at least quarterly, the likelihood and amount of potential adjustments and adjusts the income tax provision, the current tax liability and deferred taxes in the period in which the facts that give rise to a revision become probable and estimable.

Net income per share

Basic net income per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share when the combined exercise price, average unamortized fair values and assumed tax benefits upon exercise are greater than the average market price for the Company s common stock because their effect is anti-dilutive.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Effective January 1, 2009, the Company adopted FASB guidance which addresses whether instruments granted in share-based payment transactions are participating securities and therefore have a potential dilutive effect on earnings per share (EPS). This guidance was applied retroactively to all periods presented. The impact on previously reported earnings per share was not material. The following table sets forth the computation of net income per share for 2009, 2008 and 2007 (in thousands, except per share amounts):

	Years Ended December 31,								
	2009			2008			2007		
	Income	Weighted Average Shares Outstanding	Per Share Amount	Income	Weighted Average Shares Outstanding	Per Share Amount	Income	Weighted Average Shares Outstanding	Per Share Amount
Net income	91,783			106,954			86,140		
Less: Earnings allocated to unvested shareholders	(335)			(358)			(266)		
Basic EPS									
Distributable income available to common shareholders	91,448	50,356	$ 1.82	106,596	53,740	$ 1.98	85,874	52,860	$ 1.62
Effect of dilutive securities:									
Add back: Undistributed earnings allocated to unvested shareholders	335			358			266		
Dilutive stock options		609			1,045			1,495	
Less: Undistributed earnings reallocated to	(331)			(351)			(259)		

unvested shareholders									
Diluted EPS									
Common shares	91,452	50,965	$ 1.79	106,603	54,785	$ 1.95	85,881	54,355	$ 1.58

Dilutive securities include stock options and restricted stock subject to vesting. Potentially dilutive securities totaling approximately 3,926,000, 2,448,000, and 1,556,000 for the years ended December 31, 2009, 2008 and 2007, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Cash and cash equivalents

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

Marketable securities

The primary objectives of the Company s marketable security investment portfolio are liquidity and safety of principal. Investments are made with the goal of achieving the highest rate of return consistent with these two objectives. The Company s investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Marketable securities are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity under the caption Accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in Investment and interest income.

Realized gains and losses, and declines in value judged to be other-than-temporary on marketable securities, are included in Investment and interest income. The cost of securities sold is based on the specific identification

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

method. Interest and dividends on securities classified as available-for-sale are included in Investment and interest income.

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

The Company does not consider its investments in marketable securities with a current unrealized loss position to be other-than-temporarily impaired at December 31, 2009 because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at December 31, 2009 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of current portion, reflecting the Company s current intent and ability to hold such investments to maturity. The Company s investments in municipal securities are classified as available-for-sale.

Fair value of financial instruments

The carrying value of cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities approximates fair value. See Note 7 for further discussion of fair value.

Accounts receivable

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

Concentration of credit risk

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

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company limits its exposure to credit loss by placing its cash with high credit quality financial institutions. The Company generally invests its excess cash in investment grade municipal securities. The Company s marketable securities are presented in Note 6.

Inventories

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

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property, plant and equipment

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

	Years
Building	10-50
Machinery and equipment	4-8
Furniture and fixtures	3

Depreciation expense was $27.6 million, $26.5 million, and $26.6 million for the years ended December 31, 2009, 2008 and 2007, respectively. Amortization of building improvements is provided over the shorter of the remaining life of the lease or the estimated useful life of the asset.

Patent costs

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

Capitalized software costs

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

Intangible assets

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

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

Intangible assets that the Company acquires are initially recognized and measured based on their fair value. The Company uses the present value technique of estimated future cash flows to measure the fair value of assets at the date of acquisition. Those cash flow estimates incorporate assumptions based on historical experience with selling similar products in the marketplace. The useful life of an intangible asset to an entity is the period over which the asset is

expected to contribute directly or indirectly to the future cash flows of that entity. The Company amortizes the capitalized intangible assets over the remaining economic life of the relevant technology using the straight-line method, which currently ranges from 1 to 20 years.

Impairment of long-lived assets

The Company s business acquisitions typically result in the recording of goodwill and other intangible assets, and the recorded values of those assets may become impaired in the future. The Company also acquires intangible assets in other types of transactions. As of December 31, 2009, the Company s goodwill and intangible assets (excluding capitalized software), net of accumulated amortization, were $122.2 million and $172.6 million, respectively. The determination of the value of such intangible assets requires management to make estimates and

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The Company assesses the impairment of goodwill and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Impairment is reviewed at least annually, and occurs at the same time in the fourth quarter of each year, unless circumstances indicate that impairment has occurred before the fourth quarter of any given year. The Company completed its impairment test in the fourth quarter of 2009 and determined that the fair value of goodwill and long-lived assets exceeded the carrying value and therefore no impairment loss was necessary.

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

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

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

The Company s impairment analysis requires management to make assumptions and to apply judgment to estimate future cash flows and asset fair values, including estimating the profitability of future business strategies. The Company has not made any material changes in its impairment assessment methodology during the past three fiscal years. The Company does not believe there is a reasonable likelihood that there will be a material change in the estimates or assumptions it uses to calculate long-lived asset impairment losses. However, if actual results are not consistent with the Company s estimates and assumptions used in estimating future cash flows and asset fair values, the Company may be exposed to losses that could be material.

During the year ended December 31, 2008, due to certain indicators of impairment, the Company recorded impairment charges totaling $5.1 million related to its equity investment in Qualigen, Inc. and its license agreement with Corixa Corporation. Please see Notes 7 and 8, respectively, for a complete discussion of the impairment analysis.

Self-insurance reserves

The Company s consolidated balance sheets at December 31, 2009 and 2008 include approximately $1.7 million and $1.9 million, respectively, of liabilities associated with employee benefit costs that are retained by the Company, including medical costs and workers compensation claims. The Company estimates the required liability of such

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

claims on an undiscounted basis based upon various assumptions which include, but are not limited to, the Company s historical loss experience and projected loss development factors. The required liability is also subject to adjustment in the future based upon changes in claims experience, including changes in the number of incidents (frequency) and change in the ultimate cost per incident (severity).

Accumulated other comprehensive income

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

Pending adoption of recent accounting pronouncements

EITF No. 08-1

In September 2009, the FASB ratified the final consensus reached by the Emerging Issues Task Force (EITF) that revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for the Company s fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company is in the process of evaluating early prospective adoption and determining the effects, if any, the adoption of the guidance will have on its consolidated financial statements.

Note 2 Business combinations

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

Acquisition of Tepnel Life Sciences plc

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

Upon consummation of the acquisition, each issued ordinary share of Tepnel was cancelled and converted into the right to receive 27.1 pence in cash, or approximately $0.40 based on the then applicable GBP to USD exchange rate. In connection with the acquisition, the holders of issued and outstanding Tepnel capital stock, options and warrants received total net cash of approximately £92.8 million, or approximately $137.1 million based on the then applicable

GBP to USD exchange rate. The acquisition was financed through amounts borrowed by the Company under a senior secured revolving credit facility established between the Company and Bank of America, N.A. (Bank of America).

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The purchase price allocation for the acquisition of Tepnel set forth below is preliminary and subject to change as more detailed analysis is completed and additional information with respect to the fair value of the assets and liabilities acquired becomes available. The Company expects to finalize the purchase price allocation during fiscal year 2010. The preliminary allocation of the purchase price for the acquisition of Tepnel is as follows (in thousands):

Total purchase price	137,093
Exchange rate differences	(568)[1]
Allocated purchase price	$ 136,525
Net working capital	15,211
Fixed assets	11,352
Goodwill	69,995
Deferred tax liabilities	(14,148)
Other intangible assets	57,497
Liabilities assumed	(3,382)
Allocated purchase price	$ 136,525

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

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

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

The amortization periods for the acquired intangible assets with definite lives are as follows: 10 years for patents, five years for software, 12 years for customer relationships, and 20 years for trademarks and trade names. The Company plans to amortize the primary acquired intangible assets, including the customer relationships and trademarks and trade names, using the straight line method of amortization. The Company believes that the use of the straight line method is appropriate given the high customer retention rate of the acquired businesses and the historical and projected growth of revenues and related cash flows. The Company will monitor and assess the acquired customer relationships and will adjust, if necessary, the expected life, amortization method or carrying value of the customer relationships and trademarks and trade names, to best match the underlying economic value.

The fair value assigned to trademarks and trade names has been determined primarily by using the income approach and a variation of the income approach known as the relief from royalty method, which estimates the future royalties which would have to be paid to the owner of the brand for its current use. Tax is deducted and a discount rate is used to state future cash flows to a present value. This is based on the brand in its current use and is based on savings from owning the brand, or relief from royalties that would be paid to the brand owner. The fair value assigned to customer relationships has been determined primarily by using the income approach and a variation of the income approach known as the excess earnings method, which estimates the value of an asset based on discounted future earnings specifically attributed to that asset, that is, in excess of returns for other assets that contributed to those earnings. The fair value assigned to assembled workforce and software has been determined primarily by using the cost approach and a variation of the cost approach known as the cost to recreate method, which represents the cost to recreate the workforce and software at the valuation date. The fair value assigned to patents has been determined primarily by using the income approach and a variation of the income approach known

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as the discounted cash flow method, which estimates the value based on the present value of the after-tax free cash flows attributable to owning the intangible asset. The discount rates used in these valuation methods range from 12 to 13 percent.

The estimated amortization expense for these assets over future periods is as follows (in thousands):

Years Ending December 31,	
2010	$ 4,198
2011	4,198
2012	4,198
2013	4,198
2014	4,132
Thereafter	29,983
Total	$ 50,907

Approximately $5.8 million of costs associated with the Company s acquisition of Tepnel have been included in general and administrative expenses for the year ended December 31, 2009.

Acquisition of Prodesse, Inc.

In October 2009, the Company acquired Prodesse, a privately held Wisconsin corporation, for approximately $60.0 million, subject to a designated pre-closing operating income adjustment. The Company may also be required to make additional cash payments to former Prodesse securityholders of up to an aggregate of $25.0 million based on the achievement of certain specified performance measures. As a result of the acquisition, Prodesse (which is now known as Gen-Probe Prodesse, Inc.) became a wholly owned subsidiary of the Company. The Company financed the acquisition through existing cash on hand.

The purchase price allocation for the acquisition of Prodesse set forth below is preliminary and subject to change as more detailed analysis is completed and additional information with respect to the fair value of the assets and liabilities acquired becomes available. The Company expects to finalize the purchase price allocation during fiscal year 2010. The preliminary allocation of the purchase price for the acquisition of Prodesse is as follows (in thousands):

Total purchase price	$ 62,005
Net working capital	10,240
Fixed assets	644
Goodwill	32,981
Deferred tax liabilities	(21,369)

Other intangible assets	58,570
Liabilities assumed	(1,067)
Contingent consideration	(17,994)
Allocated purchase price	$ 62,005

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

In-process R&D	$ 1,070
Developed technology	24,500
Customer relationships	31,800
Trademarks / trade names	1,200
Total	$ 58,570

The amortization periods for the acquired intangible assets with definite lives are as follows: 15 years for in-process research and development (to commence upon commercialization of associated product), 12 years for developed technology, 12 years for customer relationships, and 20 years for trademarks and trade names. The Company plans to amortize the primary acquired intangible assets, including the customer relationships and trademarks and trade names, using the straight line method of amortization.

The fair value assigned to trademarks and trade names and developed technology has been determined primarily by using the income approach and a variation of the income approach known as the relief from royalty method, which estimates the future royalties which would have to be paid to the owner of the brand for its current use. Tax is deducted and a discount rate is used to state future cash flows to a present value. This is based on the brand in its current use and is based on savings from owning the brand, or relief from royalties that would be paid to the brand owner. The fair value assigned to in-process research and development and customer relationships has been determined primarily by using the income approach and a variation of the income approach known as the excess earnings method, which estimates the value of an asset based on discounted future earnings specifically attributed to that asset, that is, in excess of returns for other assets that contributed to those earnings. The discount rates used in these valuation methods range from 25 to 30 percent.

In addition to acquiring the existing Prodesse products, the Company also acquired other products that can be classified as next generation products, which are in the process of being developed. Overall an insignificant value of approximately $1.1 million was classified as in-process research and development for the products under development. The Company estimates that it will take approximately $2.4 million to complete the development of these products and, if successful in the development and approval of these products the Company anticipates related revenues starting in late 2010.

The estimated amortization expense for these assets over future periods is as follows (in thousands):

Years Ending December 31,	
2010	$ 4,752
2011	4,752
2012	4,752
2013	4,752

2014	4,752
Thereafter	32,948
Total	$ 56,708

Approximately $0.3 million of costs associated with the Company s acquisition of Prodesse have been included in general and administrative expenses for the year ended December 31, 2009.

Changes in goodwill resulting from acquisitions

The $137.1 million purchase price for Tepnel exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company allocated $70.0 million to goodwill. Included in this initial goodwill

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amount was $14.1 million related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired intangible assets.

The $62.0 million purchase price for Prodesse exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company allocated $33.0 million to goodwill. Included in this initial goodwill amount was $21.4 million related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired intangible assets.

Changes in goodwill for the twelve months ended December 31, 2009 were as follows (in thousands):

Goodwill balance as of December 31, 2008	$ 18,621
Additional goodwill recognized	102,977
Changes due to foreign translation	649
Goodwill balance as of December 31, 2009	$ 122,247

Note 3 Spin-off of industrial testing assets to Roka Bioscience, Inc.

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

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

The Company will receive royalties on any potential Roka product sales, and retain rights to use the CUDA system for clinical applications. In addition, the Company will provide contract manufacturing and certain other services to Roka on a transitional basis.

The Company has determined that Roka is not a variable interest entity and will not be included in the Company s consolidated financial statements.

Note 4 Stock-based compensation

Stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period on a straight-line basis. As of December 31, 2009, there were no outstanding equity awards with market or performance conditions. Stock-based compensation expense recognized is based on the value of share-based payment awards that are ultimately expected to vest, which

coincides with the award holder s requisite service period. A portion of these costs are capitalized into inventory on the Company s balance sheet, and are recognized as an expense when the related products are sold.

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

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The Company used the following weighted average assumptions to estimate the fair value of options granted under the Company s equity incentive plans and the shares purchasable under the Company s Employee Stock Purchase Plan (ESPP) and the resulting average fair values were as follows:

	Stock Option Plans			ESPP		
	2009	2008	2007	2009	2008	2007
Risk-free interest rate	2.0%	3.0%	4.6%	0.8%	3.3%	5.0%
Volatility	35%	34%	36%	43%	34%	29%
Dividend yield						
Expected term (years)	4.3	4.2	4.2	0.5	0.5	0.5
Resulting average fair value	$ 12.64	$ 18.36	$ 21.44	$ 11.66	$ 13.31	$ 12.88

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

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

Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of December 31, 2009
Options	2.4	$ 28,713
ESPP	0.2	268
Restricted Stock	2.3	7,881
Deferred Issuance Restricted Stock	2.7	2,022
		$ 38,884

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31,		
	2009	2008	2007
Cost of product sales	$ 3,033	$ 2,495	$ 3,144
Research and development	7,071	6,101	5,020
Marketing and sales	3,391	2,854	2,404
General and administrative	9,925	9,213	9,083
Total	$ 23,420	$ 20,663	$ 19,651

Note 5 Balance sheet information

The following tables provide details of selected balance sheet items (in thousands):

Inventories

	December 31, 2009	December 31, 2008
Raw materials and supplies	$ 13,260	$ 8,529
Work in process	23,656	24,945
Finished goods	24,155	20,932
	$ 61,071	$ 54,406

Property, plant and equipment

	December 31, 2009	December 31, 2008
Land	$ 19,268	$ 18,804
Building	80,130	80,426
Machinery and equipment	175,885	153,211
Building improvements	42,718	34,592
Furniture and fixtures	17,705	16,270
Construction in-progress	457	19

Property, plant and equipment, at cost	336,163	303,322
Less accumulated depreciation and amortization	(178,726)	(161,400)
Property, plant and equipment, net	$ 157,437	$ 141,922

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Other accrued expenses

	December 31, 2009	December 31, 2008
Contingent consideration	$ 8,396	$
Royalties	2,907	985
Professional fees	1,175	1,494
Warranty	334	923
Interest	726	
Other	4,489	625
Other accrued expenses	$ 18,027	$ 4,027

Note 6 Marketable securities

The Company s marketable securities include tax advantaged municipal securities and Federal Deposit Insurance Corporation (FDIC) insured corporate bonds with a minimum Moody s credit rating of A3 or a Standard & Poor s credit rating of A-. As of December 31, 2009, the Company did not hold auction rate securities. The Company s investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At December 31, 2009, the Company s portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody s.

The following is a summary of marketable securities as of December 31, 2009 and 2008 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2009	$ 415,236	$ 3,321	$ (95)	$ 418,462
December 31, 2008	$ 440,070	$ 6,779	$ (1,793)	$ 445,056

The following table shows the estimated fair values and gross unrealized losses for the Company s investments in individual securities that have been in a continuous unrealized loss position deemed to be temporary for less than 12 months and for more than 12 months (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated	Unrealized	Estimated	Unrealized

	Fair Value	Losses	Fair Value	Losses
December 31, 2009	$ 27,352	$ (93)	$ 2,604	$ (2)
December 31, 2008	$ 56,174	$ (628)	$ 17,606	$ (1,165)

The unrealized losses on certain of the Company s investments in municipal securities were caused by interest rate increases. At December 31, 2009 and 2008, the Company had 23 and 42 securities, respectively, in an unrealized loss position. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost of the investments. The Company does not consider its investments in municipal securities with a current unrealized loss position to be other-than-temporarily impaired at December 31, 2009 because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at December 31, 2009 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of

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current portion, reflecting the Company s current intent and ability to hold such investments to maturity. The Company s investments in municipal securities are classified as available-for-sale.

The following table shows the current and non-current classification of the Company s marketable securities as of December 31, 2009 and 2008 (in thousands):

	December 31, 2009	December 31, 2008
Current	$ 402,990	$ 371,276
Non-current	15,472	73,780
Total marketable securities	$ 418,462	$ 445,056

The following table shows the gross realized gains and losses from the sale of marketable securities, based on the specific identification method, for the years ended December 31, 2009, 2008 and 2007 (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Proceeds from sale of marketable securities	$ 371,714	$ 78,777	$ 14,811
Gross realized gains	$ 10,985	$ 1,142	$ 9
Gross realized losses	(467)	(133)	(270)
Net realized gains	$ 10,518	$ 1,009	$ (261)

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2009, by contractual maturity, are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Maturities				
Within one year	$ 42,207	$ 156	$ (51)	$ 42,312
After one year through five years	370,314	3,153	(44)	373,423
After five through ten years	2,715	12		2,727
Ten years and thereafter				

Total marketable securities	$ 415,236	$ 3,321	$ (95)	$ 418,462

Note 7 Fair value measurements

Effective January 1, 2008, the Company adopted guidance which defines fair value for financial assets and liabilities, expands disclosure requirements around fair value and specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. The Company has not elected to measure any financial assets or liabilities at fair value that were not previously required to be measured at fair value. Fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the

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Company s assumptions about the factors market participants would use in valuing the asset or liability. The guidance establishes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Assets and liabilities are based upon the lowest level of input that is significant to the fair value measurement. The Company reviews the fair value hierarchy on a quarterly basis. Changes in the observations or valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

Set forth below is a description of the Company s valuation methodologies used for assets and liabilities measured at fair value, as well as the general classification of such instruments pursuant to the valuation hierarchy. Where appropriate, the description includes details of the valuation models, the key inputs to those models, as well as any significant assumptions.

Assets and liabilities measured at fair value on a recurring basis

The Company s marketable securities include tax advantaged municipal securities, FDIC insured corporate bonds and money market funds. When available, the Company generally uses quoted market prices to determine fair value, and classifies such items as Level 1. If quoted market prices are not available, prices are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals. The Company classifies such items as Level 2.

The following table presents the Company s fair value hierarchy for assets and liabilities measured at fair value on a recurring basis (as described above) as of December 31, 2009 (in thousands):

	Fair Value Measurements at December 31, 2009			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total carrying value in the consolidated balance sheet
Assets:				
Cash equivalents	$	$ 13,000	$	$ 13,000

Marketable securities		418,462		418,462
Deferred compensation plan assets		5,671		5,671
Total assets at fair value		437,133		437,133
Liabilities:				
Contingent consideration			17,994	17,994
Deferred compensation plan liabilities		5,700		5,700
Total liabilities at fair value	$	$ 5,700	$ 17,994	$ 23,694

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For those financial instruments with significant Level 3 inputs, the following table summarizes the activity for the year ended December 31, 2009 (in thousands):

Level 3 Contingent Consideration as of December 31, 2008	$
Transfers into Level 3 from business combinations	17,994
Total realized and unrealized gains (losses):	
Included in other income, net	
Included in accumulated other comprehensive income	
Level 3 Contingent Consideration as of December 31, 2008	$ 17,994

The range of potential contingent consideration that the Company may pay related to the acquisition of Prodesse is between $0 and $25.0 million. This range is tied to multiple performance factors including financial and regulatory milestones. To the extent these milestones are earned, payments of up to $25.0 million in total will be made, most likely between the third quarter of 2010 and the first quarter of 2012. The Company has recorded $18.0 million as the fair value of this potential contingent consideration liability as of December 31, 2009. To assess the fair value of this contingent consideration the Company performed a calculation as of December 31, 2009 that contemplated the current forecasted achievement of the underlying milestones as well as the timing of the related cash payments. These amounts were discounted back to December 31, 2009 based on the discount rate established for the Prodesse acquisition as determined in the valuation and purchase price allocation work completed in the fourth quarter of 2009. The Company s calculation of the fair value of this contingent consideration as of December 31, 2009 was materially consistent with the fair value determined as of October 22, 2009, which was the date of acquisition.

Assets and liabilities measured at fair value on a non-recurring basis

Certain assets and liabilities, including cost method investments, are measured at fair value on a non-recurring basis and therefore are not included in the table above. Such instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (for example, when there is evidence of impairment).

Equity investment in public company

In April 2009, the Company made a $5.0 million preferred stock investment in DiagnoCure, Inc. (DiagnoCure), a publicly held company traded on the Toronto Stock Exchange. The Company s equity investment was initially valued based on the transaction price under the cost method of accounting. The market value of the underlying common stock is the most observable value of the preferred stock, but because there is no active market for these preferred shares the Company has classified its equity investment in DiagnoCure as Level 2 in the fair value hierarchy. The Company s investment in DiagnoCure, which totaled $5.0 million as of December 31, 2009, is included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

Equity investments in private companies

The valuation of investments in non-public companies requires significant management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such assets. The Company s equity investments in private companies are initially valued based upon the transaction price under the cost method of accounting. Equity investments in non-public companies are classified as Level 3 in the fair value hierarchy.

In September 2009, the Company spun-off its industrial testing assets to Roka, a newly formed private company. In consideration for the contribution of assets, the Company received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis. The Company s investment in Roka totaled

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approximately $0.7 million as of December 31, 2009, and is included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

In 2006, the Company invested in Qualigen, Inc. (Qualigen), a private company. The Company s investment in Qualigen, which totaled approximately $5.4 million as of December 31, 2009, is also included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

During the third quarter of 2008, the Company received financial statements from Qualigen that indicated potential issues towards the execution of their long-term sales plans. As a result, the Company performed a valuation of Qualigen. The valuation of the Company s investment was based upon several factors and included both a market approach and an income (discounted cash flow method) approach. The range of these two approaches resulted in a potential value of the Company s investment of between $4.2 and $6.6 million. The Company concluded that an equal weighting of the market and income methods was appropriate and as a result of this valuation the Company s ownership interest in Qualigen was valued at approximately $5.4 million. The Company believes that the decline in the value of this investment from its initial cost basis was an other-than-temporary impairment of its investment and thus it recorded an impairment charge of $1.6 million to write down the carrying value of its equity interest. This amount is included in Other income/(expense) on the Company s consolidated statements of income.

The Company records impairment charges when an investment has experienced a decline that is deemed to be other-than-temporary. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. Future adverse changes in market conditions or poor operating results of investees could result in losses or an inability to recover the carrying value of the investments, thereby possibly requiring impairment charges in the future. When assessing investments in private companies for an other-than-temporary decline in value, the Company considers many factors, including, but not limited to, the following: the share price from the investee s latest financing round; the performance of the investee in relation to its own operating targets and its business plan; the investee s revenue and cost trends; the investee s liquidity and cash position, including its cash burn rate; and market acceptance of the investee s products and services. From time to time, the Company may consider third party evaluations or valuation reports. The Company also considers new products and/or services that the investee may have forthcoming, any significant news specific to the investee, the investee s competitors and/or industry and the outlook of the overall industry in which the investee operates. In the event the Company s judgments change as to other-than temporary declines in value, the Company may record an impairment loss, which could have an adverse effect on its results of operations.

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Note 8 Intangible and other assets by asset class and related accumulated amortization

Intangible assets are recorded at cost, less accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives ranging from 1 to 20 years on a straight-line basis (weighted average amortization period of 8 years at December 31, 2009). The Company s intangible and other assets and related accumulated amortization consisted of the following (in thousands, except number of years):

	Weighted Avg. Amort Period (Years)	December 31, 2009			2008		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible and other assets:							
Capitalized software	10	$ 26,873	$ (14,313)	$ 12,560	$ 25,142	$ (11,733)	$ 13,409
Goodwill	N/A	$ 129,924	$ (7,677)	$ 122,247	$ 26,298	$ (7,677)	$ 18,621
License, manufacturing access fees and other assets:							
Investment in Qualigen, Inc.	N/A	5,404		5,404	5,404		5,404
Investment in DiagnoCure, Inc.	N/A	5,000		5,000			
Investment in Roka Bioscience, Inc.	N/A	725		725			
Patents	8	19,042	(17,486)	1,556	18,093	(16,817)	1,276
In-process R&D	N/A	1,070		1,070			
Purchased intangible assets	20	144,432	(37,487)	106,945	33,636	(33,338)	298
License and manufacturing access fees[1]	10	62,502	(18,326)	44,176	64,507	(18,488)	46,019
Other assets	N/A	7,740		7,740	3,611		3,611
		$ 245,915	$ (73,299)	$ 172,616	$ 125,521	$ (68,643)	$ 56,608

(1) The Company recorded an impairment charge for the net capitalized balance of $3.5 million under its license agreement with Corixa Corporation (Corixa). See complete discussion below.

In January 2008, Caris Diagnostics completed the acquisition of Molecular Profiling Institute, Inc. (MPI). Pursuant to this sale transaction, the Company s equity interest in MPI was converted into approximately $4.4 million of cash proceeds, of which $4.1 million was received in January 2008 and the remaining $0.3 million was placed into an escrow fund established to satisfy the Company s pro-rata share of indemnification obligations under the Caris/MPI merger agreement. The Company recorded a $1.6 million gain associated with the initial $4.1 million received in January 2008, and will record the remaining gain if and when any funds are released to the Company from escrow.

In May 2008, pursuant to the Company s supply and purchase agreement with F. Hoffman-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc. (together referred to as Roche), upon the first commercial sale of its CE-marked APTIMA HPV assay in Europe, the Company paid Roche $10.0 million in manufacturing access fees. Prior to and including May 2008, the Company s original payment to Roche of $20.0 million was being amortized to R&D expense. Beginning in June 2008, the additional payment of $10.0 million and any unamortized amounts remaining from the original payment are amortized to cost of product sales.

In June 2008, the Company recorded an impairment charge for the net capitalized balance of $3.5 million under its license agreement with Corixa. This charge is included in R&D expense on the consolidated statements of income. In the second quarter of 2008, a series of events indicated that future alternative uses of the capitalized intangible asset were unlikely and that recoverability of the asset through future cash flows was not considered likely enough to support continued capitalization. These second quarter 2008 indicators of impairment included decisions on the Company s planned commercial approach for oncology diagnostic products, the completion of a detailed review of the intellectual property suite acquired from Corixa, including the Company s assessment of the

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proven clinical utility for a majority of the related markers, and the potential for near term sublicense income that could be generated from the intellectual property acquired.

As of December 31, 2009, the Company had capitalized $12.1 million, net, in software costs associated with development of the TIGRIS and PANTHER instruments.

The Company had aggregate amortization expense of $12.8 million, $8.2 million and $7.6 million for the years ended December 31, 2009, 2008 and 2007, respectively, including $2.5 million relating to capitalized software in each of those years.

The expected future annual amortization expense of the Company s intangible assets is as follows (in thousands):

Years Ending December 31,	Amortization Expense
2010	$ 17,477
2011	17,440
2012	17,321
2013	17,059
2014	14,712
Thereafter	81,227
Total	$ 165,237

Note 9 Short-term borrowings

In February 2009, the Company 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. 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. Advances under the revolving credit facility are intended to be used to consummate the Company s acquisition of Tepnel and for other general corporate purposes. At the Company s option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America s prime rate and (iii) the London Interbank Offered Rate (LIBOR) plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by the Company. In connection with the credit agreement, the Company also entered into a security agreement, pursuant to which the Company secured its obligations under the credit agreement with a first priority security interest in the securities, cash and other investment property held in specified accounts maintained by Merrill Lynch, Pierce, Fenner & Smith Incorporated, an affiliate of Bank of America. In connection with the execution of the credit agreement with Bank of America, the Company terminated the commitments under its unsecured bank line of credit with Wells Fargo Bank, N.A., effective as of February 27, 2009. There were no amounts outstanding under the Wells Fargo Bank line of credit as of the termination date.

In March 2009, the Company borrowed $170.0 million under the revolving credit facility in anticipation of funding the Company s acquisition of Tepnel. Also in March 2009, the Company and Bank of America amended the credit agreement to increase the amount that the Company can borrow from time to time under the credit agreement from $180.0 million to $250.0 million. In April 2009, the Company borrowed an additional $70.0 million under its revolving credit facility with Bank of America. As of December 31, 2009, the total principal amount outstanding under the revolving credit facility was $240.0 million and the interest rate payable on such outstanding amount was 0.8%.

On February 11, 2010, the Company entered into Amendment No. 2 to Credit Agreement with Bank of America, pursuant to which, among other things, the maturity date of the Company s senior secured revolving credit

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facility was extended for an additional one-year period. As extended, the credit facility now expires on February 25, 2011.

As a result of the Tepnel acquisition, the Company assumed Tepnel s pre-existing fixed rate term loan, which accrues interest at an effective rate of 6.6%. As of December 31, 2009, the outstanding principal amount under this loan was £0.5 million, or $0.8 million based on the exchange rate of £1 to $1.59 as of the balance sheet date.

Note 10 Income tax

The components of earnings before income tax were (in thousands):

	Years Ended December 31,		
	2009	2008	2007
United States	$ 141,893	$ 160,509	$ 109,431
Rest of World	(2,091)	354	2,166
	$ 139,802	$ 160,863	$ 111,597

The provision for income tax consists of the following (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Current:			
Federal	$ 44,760	$ 48,758	$ 31,243
Rest of World	(55)	(6)	541
State	8,370	9,941	1,826
	53,075	58,693	33,610
Deferred:			
Federal	(4,390)	(4,831)	(7,816)
Rest of World	(260)	79	(26)
State	(406)	(32)	(311)
	(5,056)	(4,784)	(8,153)
Total income tax	$ 48,019	$ 53,909	$ 25,457

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Significant components of the Company s deferred tax assets and liabilities for federal and state income taxes are as follows (in thousands):

	December 31, 2009	2008
Deferred tax assets:		
Research tax credit carry-forwards	$ 2,475	$ 1,808
License, manufacturing access fees and other intangibles	1,395	1,433
Inventories	3,515	1,964
Deferred revenue	1,208	1,408
Deferred compensation	2,276	1,754
Stock compensation	21,522	16,529
Accrued vacation	2,626	2,372
Other	2,104	2,143
Net operating loss carryforwards	10,286	
Total deferred tax assets	47,407	29,411
Valuation allowance	(6,392)	(95)
Total net deferred tax assets	$ 41,015	$ 29,316
Deferred tax liabilities:		
Purchased intangibles	$ (39,203)	$
Capitalized costs expensed for tax	(5,721)	(5,681)
Property, plant and equipment	(4,223)	(2,390)
Unrealized gains on marketable securities	(1,129)	(1,745)
Total deferred tax liabilities	(50,276)	(9,816)
Net deferred tax (liability) asset	$ (9,261)	$ 19,500

At December 31, 2009, the Company had California research and development credit carry-forwards of approximately $2.8 million, which do not expire. In accordance with applicable state rules, the Company s use of its credit carry-forwards could be limited in the event of certain cumulative changes in the Company s stock ownership.

Upon the acquisition of Tepnel, the Company assumed UK tax loss carry-forwards estimated at $39.9 million. These losses do not expire, but the Company s ability to utilize these losses depends on its ability to generate future profits in the UK. The Company has established a valuation allowance of $6.2 million as of the end of 2009 against the deferred tax assets arising from these losses as the acquired UK businesses have not yet turned profitable on a consistent basis. If UK profits are earned in future periods and the losses are utilized, any reduction in the valuation allowance will result in an income tax benefit being recorded in the Company s consolidated statements of income. During the year,

approximately $4.7 million of the losses were utilized to offset gains recognized for UK tax purposes upon the sale of the BioKits food safety testing business.

Undistributed earnings of the Company s foreign subsidiaries amounted to approximately $1.1 million at December 31, 2009. The Company considers these earnings to be indefinitely reinvested, and accordingly, the Company has not provided for U.S. federal and state income taxes thereon. Upon distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes and withholding taxes payable to the foreign countries, but would also be able to offset unrecognized foreign tax credit carry-forwards. It is not practicable for the Company to determine the total amount of unrecognized deferred U.S. income tax liability because of the complexities associated with its hypothetical calculation.

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The provision for income tax reconciles to the amount computed by applying the federal statutory rate to income before tax as follows (in thousands):

	Years Ended December 31,					
	2009		2008		2007	
Expected income tax provision at federal statutory rate	$ 48,931	35%	$ 56,302	35%	$ 39,059	35%
State income tax provision, net of federal benefit	6,092	4%	7,275	5%	4,628	4%
Tax advantaged interest income	(3,394)	(2)%	(5,210)	(3)%	(3,453)	(3)%
Domestic manufacturing tax benefits	(2,795)	(2)%	(2,920)	(2)%	(1,521)	(1)%
Research tax credits	(3,100)	(2)%	(1,591)	(1)%	(1,911)	(2)%
Settlements with tax authorities		N/M%	(979)	(1)%	(11,145)	(10)%
Other, net	2,285	1%	1,032	1%	(200)	(0)%
Actual income tax provision	$ 48,019	34%	$ 53,909	34%	$ 25,457	23%

The following is a reconciliation of the cumulative unrecognized tax benefits (in thousands):

Unrecognized tax benefits as of December 31, 2007 (including the cumulative effect increase)	$ 4,603
Increase in unrecognized tax benefits for years prior to 2008	719
Increase in unrecognized tax benefits for 2008	1,326
Decrease in unrecognized tax benefits for settlements with tax authorities during 2008	(858)
Decrease in unrecognized tax benefits for lapse of statute of limitations	(37)
Unrecognized tax benefits as of December 31, 2008 (including the cumulative effect increase)	5,753
Increase in unrecognized tax benefits for years prior to 2009	294
Increase in unrecognized tax benefits for 2009	992
Decrease in unrecognized tax benefits for lapse of statute of limitations	(58)
Unrecognized tax benefits as of December 31, 2009	$ 6,981

All of the unrecognized tax benefits, if recognized, would affect the Company s effective tax rate. The Company does not anticipate there will be a significant change in the unrecognized tax benefits within the next 12 months. As of December 31, 2009 and 2008, the Company had $0.7 million and $0.5 million, respectively, in accrued interest related to unrecognized tax benefits. It is the Company s practice to include interest and penalties that related to income tax matters as a component of income tax expense.

Material filings subject to future examination are the Company s federal tax returns for the 2006 through 2008 tax years, California tax returns for the 2005 through 2008 tax years, and UK tax returns for the 2003 through 2008 tax years.

Tax benefits related to employee stock compensation programs of $2.0 million, $2.5 million, and $14.6 million for the years ended December 31, 2009, 2008 and 2007, respectively, were credited to stockholders equity.

Note 11 Stockholders equity

Stock options and restricted stock awards

The Company s stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Substantially all of the Company s full-time employees have historically participated in the Company s stock option program.

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In May 2003, the Company adopted, and the Company s stockholders subsequently approved, The 2003 Incentive Award Plan (the 2003 Plan). The 2003 Plan provides for equity incentives for officers, directors, employees and consultants through the granting of incentive and non-statutory stock options, restricted stock, performance shares, stock appreciation rights and certain other equity awards. The exercise price of each stock option granted under the 2003 Plan must be equal to or greater than the fair market value of the Company s common stock on the date of grant. Stock options granted under the 2003 Plan are generally subject to vesting at the rate of 25% one year from the grant date and 1/48 each month thereafter until the options are fully vested. Annual grants to non-employee directors of the Company vest over one year at the rate of 1/12 of the shares vesting monthly.

In May 2006, the Company s stockholders approved an amendment and restatement of the 2003 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2003 Plan by 3,000,000 shares, from 5,000,000 shares to 8,000,000 shares. Pursuant to the amended 2003 Plan, the Board of Directors or Compensation Committee, as applicable, may continue to determine the terms and vesting of all options and other awards granted under the 2003 Plan; however, in no event may the award term exceed seven years (in lieu of ten years under the 2003 Plan prior to its amendment). Further, the number of shares of common stock available for issuance under the amended 2003 Plan are reduced by two shares for each share of common stock issued pursuant to any award granted under the 2003 Plan after May 17, 2006, other than an award of stock appreciation rights or options (in lieu of a reduction of one share under the 2003 Plan prior to its amendment). In May 2009, the Company s stockholders approved a further amendment and restatement of the 2003 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2003 Plan by 2,500,000 shares, from 8,000,000 shares to 10,500,000 shares.

In November 2002, the Company adopted The 2002 New Hire Stock Option Plan (the 2002 Plan) that authorized the issuance of up to 400,000 shares of common stock for grants under the 2002 Plan. The 2002 Plan provides for the grant of non-statutory stock options only, with exercise price, option term and vesting terms generally the same as those under the 2000 Plan described below. Options may only be granted under the 2002 Plan to newly hired employees of the Company.

In August 2000, the Company adopted, and the Company s sole stockholder subsequently approved, The 2000 Equity Participation Plan (the 2000 Plan) that authorized the issuance of up to 4,827,946 shares of common stock for grants under the 2000 Plan. The 2000 Plan provides for the grant of incentive and non-statutory stock options to employees, directors and consultants of the Company. The exercise price of each option granted under the 2000 Plan must be equal to or greater than the fair market value of the Company s stock on the date of grant. Generally, options vest 25% one year from the grant date and 1/12 each month thereafter until the options are fully vested.

A summary of the Company s stock option activity for all option plans is as follows (in thousands, except per share data and number of years):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value

Outstanding at December 31, 2008	5,657	$ 44.12		
Granted	796	40.02		
Exercised	(374)	18.26		
Cancelled	(189)	51.72		
Outstanding at December 31, 2009	5,890	$ 44.96	4.4	$ 26,300
Exercisable at December 31, 2009	4,069	$ 42.51	3.8	$ 23,726

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The Company defines in-the-money options at December 31, 2009 as options that had exercise prices that were lower than the $42.92 closing market price of its common stock at that date. The aggregate intrinsic value of options outstanding at December 31, 2009 is calculated as the difference between the exercise price of the underlying options and the market price of the Company s common stock for the approximately 2,514,000 shares that were in-the-money at that date. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was $8.7 million, $12.3 million, and $45.7 million, respectively, determined as of the exercise dates.

A summary of the Company s restricted stock award activity is as follows (in thousands, except per share data):

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2008	294	$ 57.51
Granted	57	25.37
Vested and exercised	(107)	53.57
Forfeited	(15)	51.03
Unvested at December 31, 2009	229	$ 51.51

The fair value of the 107,407, 82,019, and 69,846 shares of restricted stock and deferred issuance restricted stock that vested during the years ended December 31, 2009, 2008 and 2007, respectively, was approximately $5.8 million, $4.3 million, and $3.2 million, respectively.

Additional information about stock options outstanding at December 31, 2009 with exercise prices less than or above $42.92 per share, the closing price of the Company s common stock as of December 31, 2009, is as follows (in thousands, except per share data):

	Exercisable		Unexercisable		Total	
	Number Of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
In-the-money	1,915	$ 30.53	599	$ 38.62	2,514	$ 32.46
At-the-money			25	42.92	25	42.92
Out-of-the-money	2,154	53.15	1,197	56.54	3,351	54.36
Total options outstanding	4,069		1,821		5,890	

Shares of common stock available for future grants under all stock option plans were 2,364,000 at December 31, 2009.

The weighted-average grant-date fair value per share of options granted during the periods were as follows:

	Years Ended December 31,		
	2009	2008	2007
Exercise price equal to the fair value of common stock on the grant date:			
Weighted-average exercise price	$ 40.02	$ 58.30	$ 59.11
Weighted-average option fair value	$ 12.64	$ 18.36	$ 21.44

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Employee Stock Purchase Plan

In May 2003, the Company adopted, and the Company s stockholders subsequently approved, the ESPP that authorized the issuance of up to 1,000,000 shares of the Company s common stock. The ESPP is intended to qualify under Section 423 of the Internal Revenue Code of 1986, as amended, and is for the benefit of qualifying employees as designated by the Board of Directors. Under the terms of the ESPP, purchases are made semiannually. Participating employees may elect to have a maximum of 15% of their compensation, up to a maximum of $10,625 per six month period, withheld through payroll deductions to purchase shares of common stock under the ESPP. The purchase price of the common stock purchased under the ESPP is equal to 85% of the fair market value of the common stock on the offering or Grant Date or the exercise or purchase date, whichever is lower. During the years ended December 31, 2009, 2008 and 2007, employees purchased 112,224, 97,618, and 74,337 shares at an average price of $36.49, $37.91, and $47.76 per share, respectively. As of December 31, 2009, a total of 370,754 shares were available for future issuance under the ESPP.

Stock Repurchase Program

In August 2008, the Company s Board of Directors authorized the repurchase of up to $250.0 million of the Company s common stock over the two years following adoption of the program, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. The Company completed the program in August 2009, repurchasing and retiring approximately 5,989,000 shares since the program s inception at an average price of $41.72, or approximately $249.8 million in total. When stock is repurchased and retired, the amount paid in excess of par value is recorded to additional paid-in capital.

Note 12 Derivative financial instruments

In 2009, the Company began entering into foreign currency forward contracts to reduce its exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These forward contracts generally have a maturity of approximately 30 days and were not designated as hedges. Accordingly, these instruments were marked to market at each balance sheet date with changes in fair value recognized in earnings under the caption Other income/(expense). The Company recorded a $0.9 million loss related to these derivative instruments in 2009. The Company did not have any foreign currency forward contracts outstanding at December 31, 2009.

Note 13 Commitments and contingencies

Lease commitments

The Company leases certain facilities under operating leases that expire at various dates through April 2015. In February 2008, the Company completed the acquisition of the facility where it manufactures its blood screening products, which was previously leased.

Future minimum payments under operating leases as of December 31, 2009 are as follows (in thousands):

Years Ending December 31,

2010	$ 1,326
2011	1,364
2012	1,183
2013	1,172
2014	1,046
Thereafter	252
Total	$ 6,344

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Rent expense was $1.3 million, $0.5 million, and $1.0 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Purchase commitments

The Company is currently developing a new instrument platform, called the PANTHER instrument system, designed to bring the benefits of full automation and a broad molecular diagnostics menu to low to mid-volume customers. In July 2007, the Company authorized Stratec Biomedical Systems AG (Stratec), to commence its Phase 2 development activities pursuant to its development agreement for the PANTHER instrument system. Stratec is providing services for the design and development of the PANTHER instrument system at a fixed price of $9.4 million, to be paid in installments due upon achievement of specified technical milestones, of which the Company expects $3.4 million to be paid in 2010. As of December 31, 2009, the Company had $0.9 million in outstanding purchase orders for the remaining prototype and validation instruments to be purchased in connection with the development agreement. In addition, the Company will purchase pre-production and production instruments, at specified fixed transfer prices, that will cost approximately $5.4 million in the aggregate, of which $3.8 million is expected to be spent in 2010. The Company will also purchase production tooling from Stratec at a cost of approximately $1.2 million, $0.8 million of which is expected to be spent in 2010.

The Company is obligated to purchase instruments and raw materials used in manufacturing from key vendors. The minimum combined purchase commitment was approximately $54.5 million as of December 31, 2009. Of the $54.5 million, $30.9 million is expected to be used to purchase TIGRIS instruments, of which the Company anticipates that approximately $16.0 million will be sold to Novartis.

Royalty commitments

In connection with its R&D efforts, the Company has various license agreements with unrelated parties that provide the Company with rights to develop and market products using certain technology and patent rights maintained by the parties. Terms of the various license agreements require the Company to pay royalties ranging from 1% up to 35% of future sales on products using the specified technology. Such agreements generally provide for a term that commences upon execution and continues until expiration of the last patent covering the licensed technology. Under various license agreements the Company is required to pay minimum annual royalty payments totaling $1.3 million in 2010. During 2009, 2008 and 2007, the Company recorded to cost of products sold $9.2 million, $5.2 million, and $5.0 million, respectively, in royalty costs related to its various license agreements.

Contingent Consideration

In connection with the Company s acquisition of Prodesse, the Company may be obligated to make certain payments to former Prodesse securityholders of up to $25.0 million. The aggregate fair value of these payments was $18.0 million as of December 31, 2009, and is reflected in the Company s balance sheet under the captions Other accrued expenses and Other long-term liabilities.

Litigation

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

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Digene Corporation

In December 2006, Digene Corporation (Digene) filed a demand for binding arbitration against F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. (collectively, Roche), with the International Centre for Dispute Resolution (ICDR) of the American Arbitration Association in New York. In July 2007, the ICDR arbitrators granted the Company s petition to join the arbitration. Digene s arbitration demand challenged the validity of the February 2005 supply and purchase agreement between the Company and Roche. Under the supply and purchase agreement, Roche manufactures and supplies the Company with human papillomavirus (HPV) oligonucleotide products. Digene s demand asserted, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting the Company an improper sublicense and sought a determination that the supply and purchase agreement is null and void.

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 the Company s motion to recover attorneys fees and costs from Digene in the amount of approximately $2.9 million. The Company 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. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued. The Company will record the $2.9 million as an offset to general and administrative expense upon cash receipt.

Becton, Dickinson and Company

In October 2009, the Company filed a complaint for patent infringement against Becton, Dickinson and Company (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 the Company s 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 the Company s U.S. patents covering penetrable caps for specimen collection tubes. Finally, the complaint alleges that BD has infringed the Company s U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified. The complaint seeks monetary damages and injunctive relief. There can be no assurances as to the final outcome of the litigation.

Quidel Corporation

In October 2009, Quidel Corporation (Quidel) filed a complaint against Prodesse in San Diego County Superior Court, alleging that an advertisement for Prodesse s ProFlu+ Multiplex real-time PCR assay was false and misleading. The complaint sought money damages and injunctive relief based on claims for unfair competition, false advertising, and violation of the Lanham Act. In December 2009, Quidel dismissed the complaint without prejudice, in connection with an agreement by the parties limiting re-publication of the specific advertisement at issue.

Note 14 Collaborative and license agreements

Novartis

In July 2009, the Company 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, the Company manufactures blood screening products, while Novartis is responsible for marketing, sales and service of those products, which Novartis sells under its trademarks.

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Starting in 2009, the Company is entitled to recover 50% of its manufacturing costs incurred in connection with the collaboration and will receive a percentage of the blood screening assay revenue generated under the collaboration. The Company s 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%. The Company s 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 the Company s share of blood screening assay revenue from 45 days to 30 days. Novartis is obligated to purchase all of the quantities of these assays specified on a 90-day demand forecast, due 90 days prior to the date Novartis intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

Novartis has also agreed to provide certain funding to customize the Company s PANTHER instrument for use in the blood screening market and to pay the Company 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. The parties have also agreed to evaluate, using the Company s technologies, the development of companion diagnostics for current or future Novartis medicines. Novartis has agreed to provide certain funding to the Company in support of initial research and development in this area.

During the years ended December 31, 2009, 2008 and 2007, the Company recognized revenues under this collaboration agreement in the following categories (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Product sales	$ 197,536	$ 206,283	$ 171,730
Collaborative research revenue	6,711	14,711	6,831
Royalty and license revenue	4,203	3,930	3,333
Total Revenues	$ 208,450	$ 224,924	$ 181,894

The Company also has $2.3 million in deferred license revenues under this collaboration agreement as of December 31, 2009.

Note 15 Significant customers and geographic information

During the years ended December 31, 2009, 2008 and 2007, 42%, 48%, and 45%, respectively, of total revenues were from Novartis. No other customer accounted for more than 10% of the Company s revenues in 2009, 2008, or 2007. The portions of trade accounts receivable related to Novartis were 25% at December 31, 2009 and 2008.

During the years ended December 31, 2009, 2008 and 2007, 41%, 48%, and 46%, respectively, of product sales were from the sale of commercially approved blood screening products. Other revenues related to the development of blood screening products prior to commercial approval are recorded in collaborative research revenue as disclosed in

Note 14. During the years ended December 31, 2009, 2008 and 2007, 59%, 52%, and 54%, respectively, of product sales were from the sale of clinical diagnostic products and instruments.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Total revenues by geographic region were as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Total revenue:			
North America	$ 369,790	$ 363,225	$ 322,907
Rest of World	128,512	109,470	80,107
	$ 498,302	$ 472,695	$ 403,014

Note 16 Employee benefit plan

Effective May 1, 1990, the Company established a Defined Contribution Plan covering substantially all of the Company s employees beginning the month after they are hired. Employees may contribute up to 20% of their compensation per year (subject to a maximum limit imposed by federal tax law). The Company is obligated to make matching contributions equal to a maximum of 50% of the first 6% of compensation contributed by the employee. The contributions charged to operations related to the Company s employees totaled $2.0 million, $1.8 million, and $1.6 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Note 17 Deferred compensation plan

In May 2005, the Company s Board of Directors approved the adoption of a Deferred Compensation Plan (the Plan), which became effective as of June 30, 2005. The Plan allows certain highly compensated management, key employees and directors of the Company to defer up to 80% of annual base salary or director fees and up to 80% of annual bonus compensation. Deferred amounts are credited with gains and losses based on the performance of deemed investment options selected by a committee appointed by the Board of Directors to administer the Plan. The Plan also allows for discretionary contributions to be made by the Company. Participants may receive distributions upon (i) a pre-set date or schedule that is elected during an appropriate election period, (ii) the occurrence of unforeseeable financial emergencies, (iii) termination of employment (including retirement), (iv) death, (v) disability, or (vi) a change in control of the Company, as defined in the Plan. Certain key participants must wait six months following termination of employment to receive distributions. The Plan is subject to Internal Revenue Code Section 409A.

The Company may terminate the Plan at any time with respect to participants providing services to the Company. Upon termination of the Plan, participants will be paid out in accordance with their prior distribution elections and otherwise in accordance with the Plan. Upon and for twelve (12) months following a change of control, the Company has the right to terminate the Plan and, notwithstanding any elections made by participants, to pay out all benefits in a lump sum, subject to the provisions of the Code. As of December 31, 2009, the Company had approximately $5.7 million of accrued deferred compensation under the Plan. Of that amount, $2.7 million and $3.0 million have been classified as current and long term liabilities within Accrued salaries and employee benefits and Other long-term liabilities, respectively.

Note 18 Quarterly information (unaudited)

The following tables set forth the quarterly results of operations for each quarter within the two-year period ended December 31, 2009. The information for each of these quarters is unaudited and has been prepared on the same basis as the Company s audited consolidated financial statements. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

unaudited quarterly results when read in conjunction with the Company s audited consolidated financial statements and related notes. The operating results of any quarter are not necessarily indicative of results for any future period.

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2009				
Total product sales	$ 112,522	$ 116,816	$ 118,951	$ 135,470
Total revenues	116,183	120,545	122,704	138,870
Cost of product sales (excluding acquisition-related intangibles amortization)	33,314	38,280	36,345	44,454
Gross profit	79,208	78,536	82,606	91,016
Total operating expenses	83,213	97,301	93,667	104,007
Net income	25,747	19,815	22,196	24,025
Net income per share[(1)]:				
Basic	$ 0.49	$ 0.39	$ 0.45	$ 0.49
Diluted	$ 0.49	$ 0.38	$ 0.44	$ 0.48

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2008				
Total product sales	$ 101,507	$ 113,701	$ 108,253	$ 105,759
Total revenues	122,563	119,814	121,177	109,141
Cost of product sales	32,636	32,510	30,681	32,202
Gross profit	68,871	81,191	77,572	73,557
Total operating expenses	79,547	87,002	78,805	81,946
Net income	31,945	24,791	29,078	21,140
Net income per share[(1)]:				
Basic	$ 0.59	$ 0.46	$ 0.53	$ 0.40
Diluted	$ 0.58	$ 0.45	$ 0.52	$ 0.40

(1) Amounts shown may reflect rounding adjustments.

Note 19 Subsequent event

In February 2010, the Company s Board of Directors authorized the repurchase of up to $100.0 million of the Company s common stock over the one year period following adoption of the program, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program.

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GEN-PROBE INCORPORATED

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

For The Three Years Ended December 31, 2009
(In thousands)

	Balance at Beginning of Period	Addition Charged to Cost and Expenses	Deductions[1]	Balance at End of Period
Allowance for doubtful accounts:				
Year Ended December 31, 2009:	$ 700	$ 633	$ (817)	$ 516
Year Ended December 31, 2008:	$ 719	$ 9	$ (28)	$ 700
Year Ended December 31, 2007:	$ 670	$ 130	$ (81)	$ 719
Inventory reserves:				
Year Ended December 31, 2009:	$ 5,694	$ 4,457	$ (614)	$ 9,538
Year Ended December 31, 2008:	$ 6,661	$ 1,493	$ (2,460)	$ 5,694
Year Ended December 31, 2007:	$ 5,802	$ 1,043	$ (184)	$ 6,661

[1] Represents amounts written off against the allowance or reserves, or credited to earnings.

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INDEX TO EXHIBITS

Exhibit Number	Description
2.1(2)	Separation and Distribution Agreement, dated May 24, 2002, and amended and restated as of August 6, 2002, between Gen-Probe Incorporated and Chugai Pharmaceutical Co., Ltd. (now Fujirebio, Inc.).
2.2(22)	Recommended Cash Offer for Tepnel Life Sciences plc.
2.3(23)	Implementation Agreement dated as of January 30, 2009 by and between Gen-Probe Incorporated and Tepnel Life Sciences plc.
2.4	Agreement and Plan of Merger, dated as of October 6, 2009, by and among Gen-Probe Incorporated, Prodigy Acquisition Corp., Prodesse, Inc. and Thomas M. Shannon and R. Jeffrey Harris, as the Securityholders Representative Committee.**
3.1(2)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(6)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(24)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(15)	Certificate of Elimination of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(2)	Specimen Common Stock Certificate.
10.1(15)	The 2000 Equity Participation Plan of Gen-Probe Incorporated (as last amended on November 16, 2006).
10.2(15)	The 2000 Equity Participation Plan Form of Agreement and Grant Notice for Non-Employee Directors (as last amended on November 16, 2006).
10.3(15)	The 2002 New Hire Stock Option Plan of Gen-Probe Incorporated (as last amended on November 16, 2006).
10.4(15)	The 2002 New Hire Stock Option Plan Form of Agreement and Grant Notice (as last amended on November 16, 2006).
10.5(29)	The 2003 Incentive Award Plan of Gen-Probe Incorporated (as last amended effective as of May 14, 2009).
10.6(15)	The 2003 Incentive Award Plan Form of Agreements and Grant Notices (as last amended on February 8, 2007).
10.7(11)	The 2003 Incentive Award Plan Form of Restricted Stock Award Agreement and Grant Notice, as amended.
10.8(32)	The 2003 Incentive Award Plan Form of Performance Stock Award Grant Notice and Performance Stock Award Agreement.
10.9(6)	Employee Stock Purchase Plan of Gen-Probe Incorporated, as amended.
10.10(16)	Gen-Probe Incorporated 2007 Executive Bonus Plan.
10.11(28)	2009 Gen-Probe Employee Bonus Plan.
10.12(25)	Amended and Restated Gen-Probe Incorporated Deferred Compensation Plan, effective January 1, 2008.
10.13(4)	Gen-Probe Incorporated Change-In-Control Severance Compensation Plan for Employees.
10.14(25)	Amendment to Gen-Probe Incorporated Change-in-Control Severance Compensation Plan, dated October 2, 2008.
10.15(31)	Restated Agreement dated as of July 24, 2009 by and between Gen-Probe Incorporated and Novartis Vaccines and Diagnostics, Inc.**
10.16(1)	

	Supplemental Agreement dated April 2, 2001 to the Agreement dated June 11, 1998 for Development, Distribution and Licensing of TMA Products between Gen-Probe Incorporated and Bayer Corporation.*
10.17(14)	Settlement Agreement dated August 1, 2006 among Gen-Probe Incorporated, Bayer HealthCare LLC and Bayer Corporation.*
10.18(1)	Distribution Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*

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Exhibit Number	Description
10.19(3)	Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.20(1)	Renewal Amendment dated November 2, 1999 to the Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.
10.21(1)	First Amendment dated August 4, 2000 to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.22(6)	2003 Amendment dated May 2, 2003 to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux, S.A.*
10.23(12)	2006 Amendment dated May 1, 2006 to the Renewed Distributorship Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux, S.A.
10.24(3)	License Agreement dated July 1, 2001 between Gen-Probe Incorporated and Chugai Diagnostics Science Co., Ltd. (now Fujirebio, Inc.).
10.25(3)	Distribution Agreement effective as of September 1, 1998 between Gen-Probe Incorporated and Chugai Diagnostics Science Co., Ltd. (now Fujirebio, Inc.).
10.26(3)	First Amendment dated June 30, 2002 to September 1, 1998 Distribution Agreement between Gen-Probe Incorporated and Chugai Diagnostics Science Co., Ltd. (now Fujirebio, Inc.).
10.27(3)	Co-Exclusive Agreement effective April 23, 1997 between Gen-Probe Incorporated and The Board of Trustees of the Leland Stanford Junior University.*
10.28(1)	Amendment No. 1 effective April, 1998 to the License Agreement effective April 23, 1997 between Stanford University and Gen-Probe Incorporated.*
10.29(3)	Non-Assertion Agreement dated February 7, 1997 between Gen-Probe Incorporated and Organon Teknika B.V.*
10.30(31)	Non-exclusive License Agreement under Vysis Collins Patents dated June 22, 1999 between Gen-Probe Incorporated and Vysis, Inc.
10.31(7)	Settlement Agreement under Vysis Collins Patents effective September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc.*
10.32(7)	Amendment to Nonexclusive License Agreement under Vysis Collins Patents dated September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc.*
10.33(31)	Development, License and Supply Agreement effective October 16, 2000 between Gen-Probe Incorporated and KMC Systems, Inc.
10.34(1)	First Amendment made as of September, 2001 to Agreement entered into as of October 16, 2000 between Gen-Probe Incorporated and KMC Systems, Inc.*
10.35(3)	Supply Agreement effective March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.36(1)	First Amendment effective February 21, 2001 between Gen-Probe Incorporated and Roche Diagnostics GmbH (the successor-in-interest to Boehringer Mannheim GmbH) to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.37(8)	Second Amendment dated August 31, 2004 between Gen-Probe Incorporated and Roche Diagnostics (the successor-in-interest to Boehringer Mannheim GmbH) to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*

10.38(20)	Third Amendment effective January 1, 2007 between Gen-Probe Incorporated and Roche Diagnostics (the successor-in-interest to Boehringer Mannheim GmbH) to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.39(5)	License, Development and Cooperation Agreement dated November 19, 2003 between Gen-Probe Incorporated and DiagnoCure Inc.*

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Exhibit Number	Description
10.40(13)	Amendment No. 1 to License, Development and Cooperation Agreement effective May 24, 2006 between Gen-Probe Incorporated and DiagnoCure, Inc.*
10.41(30)	Amendment No. 2 to License, Development and Cooperation Agreement, effective as of April 28, 2009, between Gen-Probe Incorporated and DiagnoCure, Inc.*
10.42(6)	Supply Agreement dated January 1, 2002 between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.43(6)	Supply Agreement Amendment Number One dated June 4, 2004 between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.44(9)	Supply and Purchase Agreement effective February 15, 2005 between Gen-Probe Incorporated, F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc.*
10.45(17)	Development Agreement for Panther Instrument System effective November 22, 2006 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG.*
10.46(17)	Supply Agreement for Panther Instrument System effective November 22, 2006 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG.*
10.47(17)	Letter Agreement regarding Development Agreement for Panther Instrument System dated July 17, 2007 between Gen-Probe Incorporated and STRATEC Biomedical Systems AG.*
10.48(26)	Credit Agreement dated as of February 27, 2009 by and between Gen-Probe Incorporated, as Borrower, and Bank of America, N.A., as Lender.
10.49(26)	Security Agreement (Securities) dated as of February 27, 2009 by Gen-Probe Incorporated in favor of Bank of America, N.A.
10.50(27)	Amendment to Credit Agreement dated as of March 23, 2009 by and between Gen-Probe Incorporated, as Borrower, and Bank of America, N.A., as Lender.
10.51(33)	Amendment No. 2 to Credit Agreement dated as of February 11, 2010 by and between Gen-Probe Incorporated, as Borrower, and Bank of America, N.A., as Lender.
10.52(30)	Amended and Restated Employment Agreement effective May 18, 2009 between Gen-Probe Incorporated and Carl W. Hull.
10.53(30)	Form of Grant Notice and Deferred Issuance Restricted Stock Award Agreement between Gen-Probe Incorporated and Carl W. Hull.
10.54(10)	Employment Offer Letter effective July 15, 2005 between Gen-Probe Incorporated and Stephen J. Kondor.
10.55(18)	Employment Offer Letter between Gen-Probe Incorporated and Christina Yang.
10.56(25)	Amendment to Offer Letter Agreement effective October 31, 2008, between Gen-Probe Incorporated and Christina Yang.
10.57(19)	Employment Offer Letter effective October 30, 2007 between Gen-Probe Incorporated and Jorgine Ellerbrock.
10.58(5)	Form of Employment Agreement Executive Team (executed by the following executive officers: D. Kacian, R. Bowen, S. Kondor, H. Rosenman, D. De Walt, J. Ellerbrock and C. Yang).
10.59(16)	Form of First Amendment to Employment Agreement for Executive Vice Presidents and Vice Presidents, effective March 1, 2007 (executed by the following officers: R. Bowen, D. De Walt, P. Gargan, D. Kacian, S. Kondor, H. Rosenman).
10.60(21)	Form of Employment Agreement Executive Team as approved in September 2008 (executed by the following executive officers: E. Tardif and E. Lai).
10.61(25)	Form of First Amendment to Employment Agreement effective October 2008 (executed by the following officers: J. Ellerbrock and C. Yang)
10.62(25)	

	Form of Second Amendment to Employment Agreement effective October 2008 (executed by the following officers: P. Gargan, R. Bowen, D. De Walt, D. Kacian, S. Kondor and H. Rosenman)
10.63(2)	Form of Indemnification Agreement between Gen-Probe Incorporated and its Executive Officers and Directors.
21.1	List of subsidiaries of Gen-Probe Incorporated.
23.1	Consent of Independent Registered Public Accounting Firm.

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Exhibit Number	Description
31.1	Certification dated February 25, 2010, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification dated February 25, 2010, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification dated February 25, 2010, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification dated February 25, 2010, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002

Filed herewith.

Indicates management contract or compensatory plan, contract or arrangement.

* Gen-Probe has been granted confidential treatment with respect to certain portions of this exhibit.

** Gen-Probe has requested confidential treatment with respect to certain portions of this exhibit.

(1) Incorporated by reference to Gen-Probe s Registration Statement on Form 10 filed with the SEC on May 24, 2002.

(2) Incorporated by reference to Gen-Probe s Amendment No. 2 to Registration Statement on Form 10 filed with the SEC on August 14, 2002.

(3) Incorporated by reference to Gen-Probe s Amendment No. 3 to Registration Statement on Form 10 filed with the SEC on September 5, 2002.

(4) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K filed with the SEC on March 24, 2003.

(5) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K filed with the SEC on March 9, 2004.

(6) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on August 9, 2004.

(7) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on November 9, 2004.

(8) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K filed with the SEC on March 15, 2005.

(9) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on May 10, 2005.

(10) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on August 1, 2005.

(11) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on December 6, 2005.

(12) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on May 5, 2006.

(13) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on August 3, 2006.

(14) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on November 1, 2006.

(15) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K filed with the SEC on February 23, 2007.

(16) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on May 1, 2007.

(17) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on November 5, 2007.

(18) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on May 2, 2007.

(19) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on November 19, 2007.

(20) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-K filed with the SEC on February 25, 2008.

(21) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed on October 31, 2008.

(22) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on January 30, 2009.

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(23) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on February 5, 2009.

(24) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on February 18, 2009.

(25) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K filed with the SEC on February 25, 2009.

(26) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on March 4, 2009.

(27) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on March 25, 2009.

(28) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed on May 6, 2009.

(29) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on May 19, 2009.

(30) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed on August 6, 2009.

(31) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed on November 5, 2009.

(32) Incorporated by reference to Gen-Probe s Report on Form 8-K with respect to Items 5.02 and 9.01 filed with the SEC on February 16, 2010.

(33) Incorporated by reference to Gen-Probe s Report on Form 8-K with respect to Items 1.01, 2.03 and 9.01 filed with the SEC on February 16, 2010.