GEN PROBE INC
Form 10-K
February 25, 2009

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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, 2008

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, par value $0.0001 per share	Nasdaq Global Select

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. **þ**

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of June 30, 2008, 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 13, 2009, 52,336,758 shares of registrant s common stock, $0.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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PART I

TRADEMARKS AND TRADE NAMES

ACCUPROBE, AMPLIFIED MTD, APTIMA, APTIMA COMBO 2, DTS, GASDIRECT, GEN-PROBE, LEADER, PACE, PANTHER, PROGENSA, SB100, TIGRIS and our other logos and trademarks are the property of Gen-Probe Incorporated. PROCLEIX and ULTRIO are trademarks of Novartis Vaccines & Diagnostics, Inc., or Novartis. VERSANT is a trademark of Siemens Healthcare Diagnostics, Inc., or Siemens. 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 discussed in 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.

ABOUT THIS ANNUAL REPORT

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.

Item 1. ***Business***

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for screening donated human blood. We also develop and manufacture nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. We market and sell our clinical diagnostic products in the

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United States directly and outside the United States primarily through distributors, as well as through our direct sales force, and we also market and sell our other products through collaborative partners.

Founded in 1983, we pioneered the scientific and commercial development of nucleic acid testing, or NAT. By utilizing nucleic acid probes that specifically bind to nucleic acid sequences known to be unique to target organisms, NAT enables detection of microorganisms that are difficult or time-consuming to detect with traditional laboratory methods. We have received United States Food and Drug Administration, or FDA, approvals or clearances for a broad portfolio of products that use our patented technologies to detect a variety of infectious microorganisms, including those causing sexually transmitted diseases, tuberculosis, strep throat, pneumonia and fungal infections. We estimate that currently our FDA-approved Procleix assay for human immunodeficiency virus (type 1), or HIV-1, and for hepatitis C virus, or HCV, and Procleix West Nile virus, or WNV, assay are utilized to screen over 80% of the United States donated blood supply for HIV-1, HCV and WNV. We have 26 years of nucleic acid detection research and product development experience, and our products are used daily in clinical laboratories and blood collection centers throughout the world. 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.

We generate revenues primarily from sales of clinical diagnostic and blood screening assays that we have developed with our proprietary technologies. We have also designed and developed, often with outside vendors, a range of instruments for use with our assays that we sell to or place with customers. Our clinical diagnostic products are marketed to clinical laboratories, public health institutions and hospitals in the United States, Canada and certain countries in Europe through our direct sales force of 39 employees. Our blood screening products are marketed and distributed worldwide by Novartis. In addition, we have agreements with Siemens (as assignee of Bayer Corporation), bioMérieux, Inc., or bioMérieux, and Fujirebio, Inc., through its subsidiary Rebio Gen, Inc., or Rebio Gen, to market products in various overseas markets. We also generate revenues through collaborations with various companies and through licensing of our patented NAT technologies.

We are developing NAT assays and instruments for the detection of harmful pathogens in the environment and biopharmaceutical and beverage manufacturing processes. We have entered into collaboration agreements with GE Infrastructure Water and Process Technologies, or GEI, a unit of General Electric Company, and Millipore Corporation, or Millipore, under which we will be primarily responsible for developing and manufacturing assays for exclusive use or sale by our collaborative partners in specified fields within the industrial testing market. Millipore launched the first product under our collaboration in January 2008.

We were 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.

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.

Product Development; Recent Events

We have developed and commercialized what we believe to be the world s first fully automated, integrated, high-throughput, NAT instrument system, the TIGRIS instrument. The TIGRIS instrument can significantly reduce labor costs and contamination risks in high-volume diagnostic testing environments and it also enables large blood

collection centers to individually test donors blood. In December 2003, we received marketing clearance from the FDA for sexually transmitted disease, or STD, testing on the TIGRIS instrument using our APTIMA Combo 2 assay that detects chlamydia and gonorrhea. The Procleix Ultrio assay for use on the TIGRIS instrument received approval to apply the Conformite Europeene, or CE, mark in December 2004, which permitted Novartis to begin commercialization of the Procleix TIGRIS instrument in the European Economic Area. In March 2007, the FDA approved the Procleix TIGRIS system to screen donated blood, organs and tissues for WNV using the Procleix WNV assay. In May 2007, the FDA approved the Procleix TIGRIS system for use with the Procleix Ultrio assay to

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screen donated blood, plasma, organs and tissues 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 hepatitis B virus, or HBV, in individual blood donations or in pools of up to 16 blood samples on the enhanced semi-automated system, or eSAS, and on the TIGRIS instrument.

In January 2008, Millipore commenced commercialization of the first MilliPROBE assay developed under our collaboration, which targets the bacterium *Pseudomonas aeruginosa* and is designed as an in-process, early warning system to provide faster, more effective detection of *Pseudomonas aeruginosa* in purified water used during drug production. The assay was designed to ensure a higher degree of water quality throughout manufacturing processes where the contaminant can be a serious quality and safety concern. We believe faster detection will enable biopharmaceutical manufacturers to reduce downstream processing risks, optimize product yields and improve final product quality.

In March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. The investigational APTIMA HPV assay is an amplified nucleic acid test that is designed to detect 14 types of high-risk human papillomavirus, or HPV, that are associated with cervical cancer. More specifically, the assay is designed to detect two 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. We expect to enroll approximately 7,000 women in the trial. Actual enrollment, however, may vary based on the prevalence of cervical disease among women in the trial. Trial enrollment and testing are expected to take approximately two years. The APTIMA HPV assay is designed to run on our TIGRIS instrument system and on our future medium-throughput instrument platforms.

In May 2008, we launched our APTIMA HPV assay in Europe. The APTIMA HPV assay has been CE-marked for use on the TIGRIS system and our semi-automated Direct Tube Sampling, or DTS, system.

In June 2008, 3M Corporation, or 3M, discontinued our collaboration to develop rapid, molecular tests for healthcare-associated infections, or HCAIs, due to technical incompatibilities between our NAT technologies and 3M s proprietary microfluidics instrument platform. Under the terms of the discontinued agreement, we were responsible for assay development, which 3M funded. 3M had also agreed to pay us milestones based on technical and commercial progress. We earned the first of these milestones, related to assay feasibility, in the fourth quarter of 2007. Based on the termination of the agreement, in June 2008 we recorded $2.7 million in collaborative research revenue that was previously deferred. In addition, we received $370,000 in wind-down costs in December 2008 as part of the termination of the collaboration. We are currently exploring other opportunities to commercialize our prototype assays in the HCAI field.

In January 2009, we extended the term of our blood screening collaboration with Novartis until June 30, 2025. The parties also agreed to customize our Panther instrument, a fully automated molecular testing platform now in development, for use in the blood screening market. In addition, the parties agreed to evaluate, using our technologies, the development of companion diagnostics for current or future Novartis medicines. For additional information regarding our recently revised blood screening collaboration with Novartis, see Corporate Collaborations and Strategic Arrangements Agreement with Novartis (formerly Chiron Corporation) below.

In January 2009, we made a recommended cash offer to acquire Tepnel Life Sciences Plc, or Tepnel, a company registered in England and Wales, for approximately $132.2 million (based on the exchange rate described in the offer). Our offer is subject to certain conditions, including approval of the offer by a majority in number representing 75% or more in value of Tepnel s shareholders entitled to vote with respect to the proposed transaction. If we are successful in our acquisition of Tepnel, we believe the acquisition will provide us access to growth opportunities in transplant

diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in the European molecular diagnostics market.

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Technology

Nucleic acid testing technology is based on detection of sequences of nucleic acids, which store and transfer genetic information in living organisms. The two main types of nucleic acids are DNA and ribonucleic acid, or RNA. DNA functions as a stable repository of genetic information, while RNA typically serves to transfer the information stored within DNA to the cell s machinery for making proteins.

DNA and RNA are both composed of chains of chemical subunits called nucleotides. There are four types of nucleotides in DNA, which differ in one chemical part called a base. The four different bases are: adenine, thymine, guanine and cytosine (abbreviated A, T, G and C). These four nucleotides form the building blocks of all DNA. The sequence of the individual A, T, G and C nucleotides in a DNA molecule encodes the genetic information that instructs the cell how to make particular proteins. Because DNA sequences determine which proteins a cell will make, the differences in a cell s DNA sequences make the cells of one organism differ from the cells of another.

Most DNA in cells exists in the form of a double-stranded structure that resembles a twisted ladder. In double-stranded DNA, the nucleotides on opposite sides of the ladder are always paired in a precise way. An A nucleotide binds only to a T nucleotide on the opposite strand, and vice versa. Likewise, a G nucleotide binds only to a C nucleotide, and vice versa. Each combination of an A nucleotide with a T nucleotide (or a C with a G) is ref to as a base pair. The way in which each type of nucleotide binds only to one other type of nucleotide is called complementary base pairing. As a result of complementary base pairing, the sequence of nucleotides on one strand of a DNA molecule necessarily determines the sequence of nucleotides on the opposite strand.

The attraction of a nucleotide sequence to its complementary sequence enables the use of pieces of nucleic acid as probes to detect the presence of a target nucleic acid in a test sample. If two complementary pieces of DNA (or RNA) are present in a solution under the right conditions, the complementary bases will come together and bind to form a double strand. This method is commonly known as nucleic acid hybridization. Nucleic acid hybridization techniques can be applied in a diagnostic test to detect an infectious organism (the target organism) by the use of a suitably labeled short nucleotide sequence or probe that is designed to bind specifically to a complementary nucleic acid sequence known to be unique to the target organism. The sample suspected of containing the infectious organism is treated to break open the organism, release its nucleic acids into the solution, and render them single-stranded, if necessary. The specific probe is then added, and conditions conducive to hybridization are established.

If the target organism is present in the sample, the probe should bind to the target organism s nucleic acids because the sequence of the probe has been designed to be complementary to them. By attaching a detectable label to a probe, it is possible to determine how much, if any, of that probe has bound to sequences from the target organism.

In order to facilitate detection of the target, it is desirable in many instances to increase the amount of target nucleic acid present in a sample by a process known as amplification. The goal of target amplification technologies such as our patented Transcription-Mediated Amplification, or TMA, method is to produce millions of copies of the target nucleic acids, which can then be detected using DNA or RNA probes.

Current Market Opportunity

Overview

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 a diagnostic result in just hours. For example, culture tests for *Mycobacterium tuberculosis* can take four to eight weeks for a traditional culture-based diagnosis, compared to only a few hours for NAT. The greater sensitivity and increased specificity of NAT 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 results and thus the number of undiagnosed individuals or individuals who are incorrectly diagnosed as having the disease. For example, the

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greater sensitivity of amplified NAT allows for the rapid, direct detection of a target organism like *Chlamydia trachomatis* in urine, even when it is present in low concentrations.

We have focused our business on market opportunities in three segments of the NAT market, clinical diagnostics, blood screening and industrial testing. The clinical diagnostic market has historically accounted for the majority of our NAT sales. According to Sannes and Associates, Inc., our products represented approximately 60% of the total chlamydia and gonorrhea tests sold in the United States in 2008. In blood screening, we estimate that currently the Procleix HIV-1/HCV assay and WNV assay are utilized to screen over 80% of the United States donated blood supply for HIV-1, HCV and WNV.

In order to address the emerging NAT market for industrial testing, in July 2005, we entered into a collaboration agreement with GEI to develop, manufacture and commercialize NAT products designed to detect the unique genetic sequences of microorganisms for GEI s exclusive use or sale in selected water testing applications. In August 2005, we entered into a collaboration agreement with Millipore to develop, manufacture and commercialize NAT products for rapid microbiological and viral monitoring for Millipore s exclusive use or sale in process monitoring in the biotechnology and pharmaceutical manufacturing industries. Finally, in November 2006, we entered into a collaboration with 3M to develop, manufacture and commercialize NAT products to enhance food safety. This agreement with 3M was terminated in December 2007 and we are seeking other opportunities to commercialize our prototype assays in the food testing field.

In January 2009, we made a recommended cash offer to acquire Tepnel for approximately $132.2 million (based on the exchange rate described in the offer). Our offer is subject to certain conditions, including approval of the offer by a majority in number representing 75% or more in value of Tepnel s shareholders entitled to vote with respect to the proposed transaction. If we are successful in our acquisition of Tepnel, we believe the acquisition will, among other things, provide us access to growth opportunities in the transplant diagnostics and genetic testing markets. Tepnel s human leukocyte antigens, or HLA, testing products are used to match donors and recipients in anticipation of transplant surgeries, as well as in the ongoing management of transplant recipients. Tepnel also sells genetic tests for cystic fibrosis, Down Syndrome and familial hypercholesterolemia, among others.

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The diagram below illustrates our understanding of the existing and emerging worldwide NAT markets, with some examples of our product targets and those of others within each category.

The Product Categories in Which We Compete

Clinical Diagnostics for the Detection of Non-Viral Microorganisms. NAT assays are currently used to detect the microorganisms causing various STDs, including chlamydia and gonorrhea, as well as those causing various other infectious diseases, such as *Mycobacterium tuberculosis*, Group A Streptococcus, Group B Streptococcus and *Staphylococcus aureus.*

Chlamydia, the common name for the bacterium *Chlamydia 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, 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.

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Tuberculosis, or TB, the disease caused by the microorganism *Mycobacterium tuberculosis*, remains one of the deadliest diseases in the world. 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. 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.

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. Two of the major causes of HCAIs are *Staphylococcus aureus* and an antibiotic resistant strain of *Staphylococcus aureus* known as methicillin-resistant *Staphylococcus aureus,* or MRSA.

Clinical Diagnostics for the Detection of Viral Microorganisms. 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.

HIV is the virus responsible for acquired immune deficiency syndrome, or 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.

HBV remains a major public health problem worldwide, though new HBV infections per year in the United States have declined significantly since the 1980s. Chronic HBV infection can lead to the development of severe and potentially fatal complications, such as cirrhosis of the liver.

Clinical Diagnostics for the Detection of Markers for Cancer. 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 addition, we have also commenced a U.S. clinical trial for our investigational APTIMA HPV assay, which is designed to detect 14 types of high-risk HPV associated with cervical cancer. According to the National Cancer Institute, cancer of the cervix affects more than 500,000 women worldwide each year.

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 serious viral threats to recipients of donated blood include HIV, HCV, WNV and HBV. In the United States, most blood collection centers perform NAT screening of donated blood by taking samples from donors of blood and then combining these samples into pools of 16 samples. These pooled samples are then tested to determine whether a virus is present. If the presence of a virus is detected, additional testing is then conducted to determine which sample in the pool contains the virus. Some blood collection centers, such as the United States military, test blood donor samples individually rather than in pools. In addition, individual donor testing, or IDT, may

be used during epidemic peaks.

Prior to the introduction of NAT for blood screening, blood collection 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. In the case of HIV-1, antibodies are detectable in the blood approximately

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22 days after infection. With HCV, the window period between the time of infection and the detection of the antibodies is much longer, approximately 70 days or more. NAT technology can narrow both window periods significantly through amplification and detection of the nucleic acid material of the viruses themselves rather than requiring the development of detectable levels of antibodies or viral antigens. According to the CDC, NAT reduces the window period for HIV-1 detection from 22 days for tests relying on HIV-1 antibodies to 12 days. We believe that NAT reduces the window period for HCV detection by approximately 50%, compared to tests relying on HCV antibodies. We believe that with IDT, NAT assays may reduce the window period for HBV detection by up to 42%, compared to HBV antibody tests for detection of HBV surface antigen. We also believe that the only practical means of accomplishing IDT for HBV detection will be through the use of a fully automated instrument, such as our TIGRIS instrument.

Industry Growth Trends

Adoption of amplified screening technology. We believe that the market for NAT-based clinical diagnostic products for the detection of non-viral microorganisms, particularly STDs, will expand due to the adoption of amplified screening technology. Amplification is particularly advantageous when screening for the presence of a microorganism when the level of that microorganism in clinical samples might be insufficient to permit detection with other methods. While potential carriers of STDs may forego diagnosis if faced with invasive methods of testing, we believe amplified NAT technology, which can use samples collected non-invasively, such as urine, will expand screening of high-risk populations and asymptomatic individuals.

Advances in automated testing. We believe that use of automated instrumentation, such as our TIGRIS instrument designed for high-throughput customers and our development-stage Panther instrument designed for low to mid-volume customers, will facilitate growth in both the clinical diagnostics and blood screening segments of the NAT market. Non-automated NAT testing generally requires highly-skilled laboratory technologists and we believe it is becoming increasingly difficult for clinical laboratories to recruit and retain these employees. We anticipate that demand for automated testing will increase as the technology is applied to diagnose new target microorganisms, including HPV. We believe the rate of market growth for testing additional microorganisms will depend heavily upon automation, as well as continuing advances in testing methodologies that address the issues of specificity, sensitivity, contamination, ease of use, time to results and overall cost effectiveness.

Increased focus on safety of blood supply. We believe blood collection centers will continue to focus on improving the safety of donated blood by adopting the most advanced blood screening technologies available. In addition, we believe that certain blood screening markets are trending from pooled testing of large numbers of donor samples to smaller pool sizes. We have already observed this trend with respect to certain sales internationally. In addition, certain blood collection centers may seek to adopt IDT for some or all organisms under certain conditions, rather than the testing of pooled samples, as automated instrumentation technologies make such testing feasible. During the peak period of the WNV season in 2007, for example, various blood collection centers used our technology and WNV assay for IDT.

Demand for improved diagnostic tests for cancer. New markers that correlate to the presence of cancer cells continue to be discovered, and we believe that once these markers have been clinically validated, there will be a large market for NAT-based cancer diagnostic products. In November 2006, we launched our CE-marked PROGENSA PCA3 assay, a prostate-cancer specific molecular diagnostic test, in the European Economic Area. Analyte specific reagents, or 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 2007, we received an aggregate of $3.6 million in awards for the development of improved cancer diagnostic assays from the U.S. Army Medical Research and Material Command, which actively manages research programs for the Department of Defense.

In March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. The investigational APTIMA HPV assay is an amplified nucleic acid test that is designed to detect 14 types of high-risk HPV that are

associated with cervical cancer. More specifically, the assay is designed to detect two 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 DNA. In addition, in May 2008, we launched our APTIMA HPV assay in Europe. The APTIMA HPV assay has been CE-marked for use on the TIGRIS system and our DTS system.

Emerging opportunities in industrial testing market for rapid molecular methods. We believe that significant new opportunities are emerging for NAT-based products in various industrial market segments, including quality control testing in biopharmaceutical and beverage manufacturing processes and testing for harmful contaminants in the environment and industrial water. We believe the move to rapid molecular methods is being driven by economic factors, as well as regulatory factors such as the FDA s Process Analytical Technology initiative, to encourage pharmaceutical companies to adopt rapid methods to test their manufacturing processes for the presence of objectionable organisms. We believe our collaborations with GEI and Millipore will facilitate our development of new products for, and access to, these new markets. Millipore launched the first such product under our collaboration in January 2008.

We believe additional emerging non-clinical markets for NAT include food testing, personal care products manufacturing processes and bioterrorism detection testing. Today, these markets predominately use traditional methods for microbiological testing, such as culture. However, we believe NAT testing has the potential to provide more rapid and efficient tests in these markets. Here again, we believe regulatory factors will play a role in shifting to molecular testing methods. In November 2007, for example, the FDA released a Food Protection Plan that advocates the validation and implementation of real-time diagnostic methods that allow for rapid, on-site analysis of food samples. We are currently seeking opportunities to commercialize our prototype assays in the food testing field that were developed under our collaboration with 3M, which terminated in December 2007.

Development of other emerging markets for NAT technology. 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 utilized 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 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. Nucleic-acid based testing for SNPs and other genetic anomalies can be used to determine an individual s predisposition to such conditions as thrombosis or bloodclotting. Our license of bioMérieux s intellectual property rights for the factor V and prothrombin mutation tests could allow us to access this market.

Improvements in detection technologies. Many current amplified nucleic acid tests provide an end point result, requiring that the amplification and detection processes be completed before a result is obtained. New technology permits kinetic or real-time detection of target analytes as amplification proceeds, permitting conclusions to be drawn before the amplification process is complete, and thereby reducing the time to result. Real-time detection methods are

also capable of providing both a qualitative and quantitative result from a single test. Several companies have introduced initial real-time products. For example, Abbott Laboratories has been approved to apply the CE mark to a real-time test for the simultaneous detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, allowing the test to be marketed in the European Economic Area. In April 2005, Roche was approved to apply the CE mark to its real-time COBAS AmpliPrep/COBAS TaqMan tests for HIV-1, HCV, and HBV. Roche was also approved to apply the CE mark to a real-time test for *Chlamydia trachomatis*. We intend to develop assays for our collaborations with GEI and Millipore using real-time technology. Millipore launched the first such product under our collaboration in January 2008. In addition, our prototype assays in the food testing and HCAI fields developed under our former collaborations with 3M incorporate real-time technology.

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Our Competitive Strengths

Our competitive strengths form the foundation for our business and we believe position us to compete effectively within the NAT market.

Proprietary Core Technologies

We believe that we have developed one of the broadest portfolios of NAT technologies in the industry. Our products incorporate these technologies, which, in combination, have significantly advanced our NAT assays, and we believe can make them more specific, more sensitive, easier to use and faster to result than products based on competing NAT technologies. For example, our proprietary TMA technology offers some significant advantages over other available amplification methods, including Polymerase Chain Reaction, or PCR. We believe TMA technology allows our products to offer a higher degree of sensitivity, less risk of contamination and greater ease of use than our competitors amplified products. We believe our target capture technology, which is used to extract either molecules with specific target sequences or all genetic material from a complex clinical specimen, can remove inhibitory substances that interfere with amplification, can be easily automated, and can be performed quickly. In the past, we have leveraged our core technologies to develop products that have achieved leading positions in new NAT markets, such as blood screening and STD testing. We plan to continue to use our core NAT technologies, and technologies that we may acquire, as a platform for the development of additional products addressing opportunities in existing and emerging segments of the NAT market.

Extensive Range of FDA-Approved Products and Intellectual Property Portfolio

We believe that we are unique in offering our customers a broad range of both non-amplified and amplified NAT assays, as well as multiple instruments on which to perform these assays. Our expertise in NAT products has enabled us to develop FDA-approved products for the detection of microorganisms causing infectious diseases. In February 2002, we received FDA approval for the Procleix HIV-1/HCV assay. In December 2005, the FDA approved our WNV assay for use on eSAS to screen donated human blood for WNV, and in March 2007 we received approval of our WNV assay for use on the TIGRIS instrument. In October 2006 and May 2007, the FDA granted marketing approval for use of the Procleix Ultrio assay on 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 on the TIGRIS system. Our FDA-approved NAT assays are currently performed on our proprietary luminometers and DTS and TIGRIS (in the case of our APTIMA Combo 2 and WNV assay) instruments. As of December 31, 2008, we had more than 470 United States and foreign patents covering our products and technologies, and we proactively pursue an aggressive patent strategy designed to protect both existing products and new innovations.

Innovative Product Research and Development

As of December 31, 2008, our research and development group consisted of 227 full-time employees, 97 of whom hold advanced degrees. From our PACE family of products to our amplified APTIMA Combo 2 assay, which are sufficiently sensitive to be able to detect both chlamydia infections and gonorrhea in urine samples from symptomatic or asymptomatic patients, the Procleix Ultrio assay that detects HIV-1, HCV and HBV in donated blood, and our CE-marked APTIMA HPV assay that is designed to detect 14 types of high-risk HPV that are associated with cervical cancer, our scientists have developed proprietary assays that have brought significant innovation to the market for clinical diagnostics and blood screening. To complement these products, we have developed and continue to develop automated instrumentation technologies that enable our customers to increase throughput while improving accuracy in a cost-effective manner. We have developed, and launched in 2004, what we believe to be the world s first fully

automated, integrated, high-throughput, NAT instrument system, known as the TIGRIS instrument. We are currently developing a new automated instrument platform, called the Panther instrument system, designed for low to mid-volume customers. In addition, under our license agreement with Qualigen, Inc., or Qualigen, we have conducted feasibility research and development for a closed unit dose assay, or CUDA, instrument and an associated reagent pouch, which we believe may offer potential advantages in industrial testing and other applications. We were awarded a 2004 National Medal of Technology, the nation s highest honor

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for technological innovation, in recognition of our pioneering work in developing NAT tests to safeguard the nation s blood supply.

Brand Recognition

We believe that we benefit from significant brand name recognition and customer loyalty among laboratories, blood collection agencies and physicians in the market for NAT assays. We believe our history of technological innovation, quality manufacturing, comprehensive sales capabilities and commitment to customer support has resulted in customer satisfaction and retention. We estimate that greater than 95% of our STD product sales during 2008 were to repeat customers. We believe that our brand name also facilitates market acceptance of our new products, providing us with opportunities for growth. Based on information we receive from Novartis, we believe that since 1998 the Gen-Probe/Novartis collaboration has been the sole supplier of NAT assays for blood screening to the American Red Cross, which we believe exemplifies our standing in the industry.

Sales and Technical Support Capabilities

As of December 31, 2008, our direct sales force consisted of 39 employees and a 47 member technical field support group. Our direct sales force targets the United States, Canada and certain countries in Europe. We believe that these individuals comprise one of the most knowledgeable and effective sales and support organizations in the molecular diagnostics industry. Our sales representatives have an average of approximately 17 years of overall sales experience, with an average of approximately 11 years focused on sales of NAT products. 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. We complement our sales force with leading international distributors and the direct sales organizations of our collaborative partners.

Regulatory and Quality Assurance Experience

Our products, design control and manufacturing processes are regulated by numerous third parties, including the FDA, foreign governments, independent standards auditors and customers. Our team of 139 regulatory, clinical and quality assurance professionals has successfully led us through multiple quality and compliance inspections and audits. We began production in our blood screening product manufacturing facility in 1999. This 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. In addition, we have obtained EN 13485 certification from TÜV Rheinland of North America, a leader in independent testing and assessment services. In addition, our regulatory and quality assurance departments have coordinated audits by Lloyds Register Quality Assurance leading to EN ISO 13485, EN ISO 9001, EN ISO 14001 and OHSAS 18001 certifications for our wholly owned U.K. subsidiary, Molecular Light Technology Research Limited. 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.

Our Growth Strategy

We have successfully created and maintained a leadership position in a number of segments of the NAT testing market. From this strong position, we plan to grow our business through the following strategies:

Establish Leadership Positions in New Markets by Leveraging Our Core Technologies

We have had a successful track record in identifying new product and market opportunities and becoming the market leader in a number of NAT testing segments by providing innovative product solutions based on our proprietary technology base. In the past, we have utilized our patented technology portfolio, innovation and market development expertise to establish leadership positions in areas such as chlamydia and gonorrhea testing. Our ability to strategically identify and assume leadership roles in new markets was evidenced by our entrance into the blood screening market. We successfully developed the first FDA-approved NAT assay for HIV-1/HCV detection, the Procleix HIV-1/HCV assay, which we estimate is currently being used to screen more than 80% of the United States blood supply.

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We are exploring opportunities to develop new products for emerging NAT markets. We acquired exclusive worldwide diagnostic rights to the PCA3 gene from 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 November 2006, we CE marked our PROGENSA PCA3 assay, a prostate-cancer specific molecular diagnostic test, allowing it to be marketed in the European Economic Area. Our ASRs for detection of the PCA3 gene are also available in the United States.

We also have two collaborations in the industrial testing market. We believe our collaborations with GEI and Millipore, pursuant to which each will manage worldwide commercialization of any products resulting from the respective collaboration, will enable us to access large customer bases in the markets for industrial-water and biopharmaceutical process testing, respectively. In January 2008, Millipore commenced commercialization of the first MilliPROBE assay under our collaboration, which targets the bacterium *Pseudomonas aeruginosa* and is designed as an in-process, early warning system to provide faster, more effective detection of *Pseudomonas aeruginosa* in purified water used during drug production.

In November 2007 and June 2008, 3M discontinued our collaborations for the development and commercialization of NAT products to enhance food safety and for HCAIs, respectively. Prior to the termination of these collaborations, we achieved certain technical milestones with our prototype assays, entitling us to payments from 3M of $2.0 million relating to our prototype assays to enhance food safety and $2.7 million relating to our prototype HCAI assays. We are currently exploring other opportunities to commercialize our prototype assays in these fields.

Deliver Proprietary Automated and Fully Integrated Systems for NAT Assays

We intend to continue to develop instruments that complement our existing and anticipated product lines for use in clinical diagnostics, blood screening and industrial testing. The TIGRIS instrument is designed to significantly reduce the time, labor costs, risk of contamination and complexity associated with performing NAT assays. The automation and increased throughput of the TIGRIS instrument enables blood collection centers to process the large testing volumes necessary to screen each individual unit of donated blood for the presence of life-threatening viruses. In addition to the TIGRIS instrument, we are currently developing our Panther instrument system, a new automated instrument platform designed for low to mid-volume customers. We believe this approach of providing our customers with the latest generation of systems solutions will allow us to reinforce our market position and brand recognition and to penetrate new markets.

Expand Our Clinical Diagnostics and Blood Screening Businesses with New Products

We intend to continue to broaden our product offerings through the introduction of new products to serve the clinical diagnostics and blood screening markets. With an aim to expand our offerings in the clinical diagnostics field, we started U.S. clinical trials for our investigational APTIMA HPV assay in March 2008. The investigational APTIMA HPV assay is an amplified nucleic acid test that is designed to detect 14 types of high-risk HPV that are associated with cervical cancer and is designed to run on our TIGRIS instrument system and on our future medium-throughput instrument platforms. In May 2008, we launched our APTIMA HPV assay in Europe, which has been CE-marked for use on the TIGRIS system and our DTS system.

We use a systems approach to product development, which involves combining elements of our core proprietary technologies to create products that best meet our customers needs. For example, the Procleix Ultrio assay, which we developed in collaboration with Novartis, adds an assay for HBV to the previously approved Procleix HIV-1/HCV assay and is designed to detect the presence of all known HIV-1 groups and subtypes and HCV and HBV genotypes in human plasma during the very early stages of infection, when those agents are present but cannot be detected by

immunoassays. The Procleix Ultrio assay uses our target capture, TMA and Dual Kinetic Assay, or DKA, technologies.

By understanding how our technologies complement one another and by combining reagents in our new products, we expect to capitalize on the substantial product development work that we invested in existing products. We believe that this approach and our experience in bringing FDA-cleared products to market will reduce

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development cycle times for new products, which, in turn, will help us expand our menu of clinical diagnostic and blood screening products.

Pursue Future Licensing and Acquisition Opportunities

We continually evaluate technology and other acquisition opportunities, and have historically supplemented our internal research and development efforts by obtaining licenses to new technologies. To maintain our leadership position in NAT testing, we intend to selectively obtain rights to complementary technologies through licenses and pursue corporate acquisitions. For us to enter emerging NAT markets such as cancer testing, genetics, pharmacogenomics and industrial testing, we may need to obtain rights both to new technologies and to disease markers that are discovered and clinically validated by third parties. For example, in 2003, we signed a license and collaboration agreement with DiagnoCure to develop an innovative urine test to detect the PCA3 gene marker for prostate cancer. 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 June 2008, following a bid by Solvay Pharmaceuticals, we launched a conditional counterbid to acquire Innogenetics NV, a Belgian molecular diagnostics company. We subsequently withdrew our counterbid to acquire Innogenetics in July 2008, following the submission by Solvay Pharmaceuticals of a higher bid.

In January 2009, we made a recommended cash offer to acquire Tepnel for approximately $132.2 million (based on the exchange rate described in the offer). Our offer is subject to certain conditions, including approval of the offer by a majority in number representing 75% or more in value of Tepnel s shareholders entitled to vote with respect to the proposed transaction. If we are successful in our acquisition of Tepnel, we believe the acquisition will provide us access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in the European molecular diagnostics market.

Pursue Collaborative Relationships to Accelerate New Product Development and Enhance Our Global Marketing Capabilities

We will pursue collaborative relationships that enable us to implement our strategies, particularly with respect to the development of new products and entry into new markets. We seek to partner with industry leaders who can offer access to intellectual property or who can complement our commercialization capabilities by distributing co-developed products through their sales organizations. For example, our collaboration with Novartis for the blood screening market has allowed us to combine our NAT technology with Novartis patent portfolio relating to HIV and HCV and to leverage Novartis distribution and sales resources. Further, we believe our collaborations with GEI and Millipore, pursuant to which each will manage worldwide commercialization of any products resulting from the respective collaboration, will enable us to access large customer bases in the markets for industrial-water and biopharmaceutical processes testing, respectively. In addition, we are currently exploring other opportunities to commercialize our HCAI and food testing prototype assays that were developed under our former collaborations with 3M.

Our Proprietary NAT Technologies

We have developed technologies that make NAT assays practical and effective for commercial use, thereby overcoming many of the limitations of previous DNA probe assays that restricted their use to research laboratories. Our products incorporate a combination of patented technologies that have significantly advanced NAT assays, and can make them more specific, more sensitive, easier to use and faster to result than products based on competing

technologies. These technologies include the following:

targeting of ribosomal RNA, or rRNA;

target capture/nucleic acid extraction technology;

Transcription-Mediated Amplification technology, or TMA;

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chemiluminescent detection using Hybridization Protection Assay and DKA technologies;

fluorescent real-time detection technology; and

APTIMA technology.

Together, these technologies have allowed us to commercialize new diagnostic tools that provide results in hours instead of days or weeks. This has led to quicker time to result and diagnosis, thereby making a difference in patient treatment and outcome.

Targeting Ribosomal RNA. We have developed and patented a technique that detects and identifies organisms by targeting their rRNA. The major benefits in targeting rRNA include the following:

Each bacterial cell contains up to 10,000 copies of rRNA, as compared with only a few copies of DNA. Most of our competitors NAT assays target DNA, which is present in only one or two copies in each target organism cell. Therefore, by using a probe that hybridizes to rRNA, the sensitivity of the test is increased thousands of times. This has allowed us to develop indirect and direct probe tests that are used with cultured samples or samples drawn directly from the patient;

The high number of rRNA targets also offers significant advantages when target-amplified assays are used. When very small numbers of organisms are present in a sample, they may not be present in the portion of the sample used for the assay, despite being present in the sample. This would result in a negative test result. By breaking open the organism prior to sampling, the multiple copies of rRNA targets are dispersed throughout the sample volume and the likelihood of detecting them is increased many fold. Thus, the likelihood of obtaining a false negative result is significantly less than is the case when DNA is targeted;

rRNA molecules naturally exist as single strands that can directly hybridize with our chemiluminescent; and labeled DNA probes. This is in contrast to most DNA targets, which exist as double strands that must be separated before a probe can bind. These separated DNA strands tend to hybridize to each other rather than to the DNA probe, thus limiting the amount of DNA probe that can bind and the overall sensitivity of the test; and

rRNA molecules unique to the organism are present in all bacteria, fungi and parasites. This gives us the ability to design diagnostic products for emerging infectious diseases caused by these pathogens.

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.

Target capture offers the following benefits:

concentration of nucleic acid target(s) from large volume samples, without the need for centrifugation steps;

elimination of potential inhibitors of amplification;

increased ability to test a variety of clinical samples, including urine and blood;

capture of multiple targets by using capture probes that hybridize to one or more specific nucleic acid sequences; and

enhanced specificity through selective capture of target and removal of contaminants that may produce a false positive signal.

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Transcription-Mediated Amplification. 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.

Many amplification-based NAT assays used routinely in clinical laboratories utilize a technology known as PCR to amplify DNA. With additional steps, PCR also can be used to amplify RNA. Since most organisms contain only one or two copies of DNA, there are fewer target molecules to initiate amplification when DNA targets are used, and sometimes amplification does not begin at all. In such cases, assays using PCR can fail to produce results. PCR also uses repeated heating and cooling steps, requiring complex and expensive thermocyclers. Because PCR produces large amounts of DNA, which, unlike RNA, is a stable molecule, there is an increased risk of cross-contamination from one PCR assay to another, potentially leading to a high number of false positive results.

Our patented TMA technology is designed to overcome problems faced by other target amplification methods such as PCR. 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.

TMA offers the following benefits:

- The TMA process takes place in one tube at one temperature without the need of thermocyclers required by PCR. All reagents are added to the tube and nothing is removed. This makes the test simpler to use and suitable for automation, and it minimizes the possibility of carry-over contamination and false positive test results;

- The RNA nucleic acid that is synthesized in the TMA reaction, or amplicon, is much more unstable when outside the reaction tube than the DNA that is produced in the PCR method. This instability of the TMA amplicon in the general laboratory environment reduces the possibility of carry-over contamination;

- TMA is able to amplify RNA and DNA targets, whereas PCR requires additional reagents and steps to amplify RNA; and

- TMA can be used in end-point chemiluminescent assays as well as real-time qualitative and quantitative fluorescent assays.

Chemiluminescent Technologies and Hybridization Protection Assay. Most of our current DNA probe products use chemiluminescent acridinium ester, or AE molecules, to generate light as a label for detection. When AE-labeled DNA probes are mixed with chemical activators, a light signal is produced. Various competitors DNA probe assays and immunoassays use enzyme or radioisotope labels. Assays that use enzyme-labeled DNA probes are complex and can be inhibited by contaminants present in the sample. Radioisotopes offer a strong signal but are difficult to handle, difficult to dispose of and dangerous because they give off harmful radiation.

We have simplified testing, further increased test sensitivity and specificity, and increased convenience with our patented Hybridization Protection Assay, or HPA, technology. With HPA, we introduced the first NAT assay that did not require the cumbersome wash steps needed with conventional probe tests and immunoassays. In the HPA process, the 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 reagent is added to the specimen, only the label attached to the hybridized probe is left to produce a signal indicating the target organism s DNA or RNA is present. All of these steps occur in a single container and without any wash steps.

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.

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Fluorescent Real-Time Detection Technology. In addition to HPA chemiluminescent detection assays, we have developed a series of real-time fluorescent assay systems. These assays couple TMA, or versions of TMA, with fluorescent probe detection that gives reduced times of appearance of fluorescent outputs with increasing amounts of input amplified target nucleic acid. In these assay formats, amplification and detection take place simultaneously. As a result, the total time necessary to obtain a result can be reduced significantly. We have several types of probes for these assays, including probes that we have patented and probes that we have licensed from third parties.

APTIMA Technology. We have combined target capture, TMA and HPA together into an integrated family of technologies known as APTIMA. APTIMA assays are highly refined amplification assays, simplifying sample handling, minimizing contamination and allowing for the simultaneous detection of two analytes in one tube. APTIMA assays offer clinical laboratories the significant advantage of carrying out all steps of the assay in a single tube. We believe APTIMA thereby increases assay performance, reduces laboratory costs and improves laboratory efficiency. APTIMA technology combined with automation such as the TIGRIS instrument supports true walk-away automation, allowing hundreds of specimens to be tested by an individual technician in a single run.

Our Products

We have applied our core technologies to develop multiple product lines, all of which utilize our expertise in NAT probes, sample collection and processing. We currently categorize our products into clinical diagnostic products and blood screening products. In January 2008, Millipore launched our first product in the industrial market.

Clinical Diagnostic Products

Within our clinical diagnostic product group, we have developed products for the detection of non-viral and viral microorganisms and for the detection of markers for cancer.

Clinical Diagnostic Products for the Detection of Non-Viral Microorganisms

We have developed FDA-approved amplified and non-amplified NAT assays that detect non-viral micro-organisms primarily for use in clinical diagnostics. 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 segment. Our principal products for the detection of non-viral microorganisms include our non-amplified AccuProbe and PACE family of products and our amplified Mycobacterium Tuberculosis Direct Test and amplified APTIMA products, as set forth below.

Product Line	Principal Technologies	Target Microorganism	FDA Clearance/Approval	Commercial Distribution
AccuProbe Culture Identification	Non-amplified detection of organisms from culture isolates by using rRNA as the target and Hybridization Protection Assay	*Blastomyces dermatitidis*	September 1990	Gen-Probe North America bioMérieux, Rebio Gen and other distributors Rest of World
		Campylobacter	November 1989	
		Coccidioides immitis	October 1990	
		Enterococcus	November 1989	
		Histoplasma capsulatum	February 1990	
		Haemophilus influenzae	March 1990	
		Group B Streptococcus	November 1989	
		Group A Streptococcus	November 1990	
		Mycobacterium avium Complex	May 1990	
		Mycobacterium avium	August 1990	

Mycobacterium gordonae	April 1990
Mycobacterium intracellulare	August 1990
Mycobacterium kansasii	November 1990
Mycobacterium tuberculosis Neisseria gonorrhoeae	April 1990
Streptococcus pneumoniae	November 1989
Staphylococcus aureus	August 1990
Listeria monocytogenes	August 1990
	June 1990

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Product Line	Principal Technologies	Target Microorganism	FDA Clearance/Approval	Commercial Distribution
GASDirect	Non-amplified detection of rRNA from a swab sample by Hybridization Protection Assay	Group A Streptococcus	March 1994	Gen-Probe North America bioMérieux, Rebio Gen and other distributors Rest of World
PACE Product Family	Non-amplified detection of rRNA from patient sample by Hybridization Protection Assay	*Chlamydia trachomatis* and *Neisseria gonorrhoeae*, including combined detection	PACE December 1987 PACE 2 April 1992 PACE 2C October 1994	Gen-Probe North America bioMérieux, Rebio Gen and other distributors Rest of World
Mycobacterium Tuberculosis Direct Test (or MTD)	Transcription-Mediated Amplification of rRNA in patient sample and detection by Hybridization Protection Assay	*Mycobacterium tuberculosis*	December 1995	Gen-Probe North America bioMérieux, Rebio Gen and other distributors Rest of World
APTIMA Combo 2	Target Capture, Transcription-Mediated Amplification of rRNA and detection by Dual Kinetic Assay	*Chlamydia trachomatis* and *Neisseria gonorrhoeae*	May 2001	Gen-Probe North America Europe Rebio Gen Japan
APTIMA CT APTIMA GC	Target Capture, Transcription-Mediated Amplification of rRNA and detection by Dual Kinetic Assay	*Chlamydia trachomatis* and *Neisseria gonorrhoeae*	December 2004 March 2005	Gen-Probe North America Europe
APTIMA Trichomonas ASR	Target Capture, Transcription-Mediated Amplification of rRNA	*Trichomonas vaginalis*	Not required	Gen-Probe U.S.

AccuProbe Products. Our AccuProbe Culture Identification products are powerful tools for the identification of mycobacterial, fungal and bacterial pathogens, with sensitivities and specificities approaching 100% in most cases. These products allow for the detection of target organisms from primary cultures, eliminating the additional labor of purifying secondary cultures. All AccuProbe Culture Identification assays are based on our HPA technology. All of our AccuProbe Culture Identification tests follow a standard format, use common reagents and do not require highly trained technical personnel. Results are obtained utilizing our luminometers, which are easy to use and offer precise readings. In addition, the convenient packaging provides extended stability and shelf life. As part of our AccuProbe Culture Identification product line, we have also developed a procedure to detect GBS from broth culture. The assay demonstrates near 100% sensitivity and specificity when testing broth samples after 24 hours of incubation. Our products address the market need for a more rapid, direct test procedure for GBS that can be used to effectively screen women during pregnancy and to provide prompt results when testing is performed just before delivery.

Group A Streptococcus Direct. The 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. Sensitivity and specificity are equivalent to culture methods taking 72 hours to complete and are higher than the rapid membrane antigen tests often used in physician offices. The test provides fast and accurate results, eliminates subjective interpretation by the laboratory technician, and aids physicians in making more informed treatment decisions. The product s ease of

use enables efficient batch testing. An automatic pipetting option offers greater workflow economies and laboratory productivity.

PACE Product Family. Our PACE 2C was the first advanced NAT product to offer the convenience of testing for both chlamydia infections and gonorrhea from a single patient specimen. This feature eliminates the need to collect separate specimens and the need to transport the specimens under different conditions. The PACE 2C continues to meet the needs of clinical laboratories that prefer a cost-effective, non-amplified NAT assay for routine screening for chlamydia infections and gonorrhea. Other products in the PACE 2 product line include individual tests to separately detect and confirm both chlamydia infections and gonorrhea. The PACE product family also includes the PACE Specimen Collection kits for endocervical and urethral swab specimens. Sales of our PACE family of assays have declined in recent years as we are actively working to convert our PACE 2C customers to our amplified APTIMA Combo 2 product line which, while partially decreasing PACE family revenues, ultimately contributes to total clinical diagnostic product sales growth.

Mycobacterium Tuberculosis Direct Test. Amplification is particularly important when detecting pathogens present at low levels, as is often the case with tuberculosis. Culture tests for TB can take four to eight weeks for a preliminary result. 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. The test is performed directly on a patient sample, and can be used to quickly differentiate between TB and other mycobacteria, resulting in reduced isolation time and treatment of an infected patient. Our MTD test was the first amplified NAT assay for obtaining same day results from sputum samples.

APTIMA Combo 2. To meet market demand for amplified STD assays, we developed our APTIMA Combo 2 assay, which received FDA clearance in May 2001 and was launched commercially in August 2001. Acceptance of first generation amplified tests was adversely affected by the complexity of the methodology and the lack of a format suitable for use in the average laboratory. APTIMA Combo 2, which uses second generation amplification technologies, allows us to overcome these barriers. The test offers superior performance and ease of use, including the use of a penetrable cap that eliminates the need to uncap samples prior to testing and a sample transport medium that preserves the integrity of the sample for several weeks at room temperature.

We believe the assay is ideally suited to test specimens from both symptomatic and asymptomatic individuals. Symptomatic individuals typically have large amounts of the microorganism present at the infection site, while patients who are asymptomatic typically have much lower levels of the microorganism present at the infection site.

In addition to amplification technology, our APTIMA Combo 2 assay utilizes our target capture HPA and DKA technologies. APTIMA Combo 2 will qualitatively detect and differentiate rRNA from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* bacteria. This continues the one test, two results advantage we first provided with our PACE 2C non-amplified assay for chlamydia infections and gonorrhea. We believe we are in a unique position to provide both amplified and non-amplified NAT assays for these infections. This allows us to compete effectively in the STD testing market and to provide the appropriate NAT solution to meet the needs of many different customers.

Our APTIMA Combo 2 assay is the first clinical diagnostic assay approved for use on the fully automated TIGRIS instrument. Our APTIMA Combo 2 assay is also performed on our semi-automated DTS instruments. In January 2004, we received FDA clearance to use the APTIMA Combo 2 assay with the APTIMA Vaginal Swab Specimen Collection Kit, the first kit that enables patients to self-collect vaginal swab specimens.

In August 2005, the FDA granted marketing clearance to use the APTIMA Combo 2 assay to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from liquid Pap specimens collected and processed with Cytyc Corporation s ThinPrep® 2000 system. This new use provides physicians the convenience of intercepting chlamydia and gonorrhea

from the same sample collected for the ThinPrep® Pap Test. The Pap test remains the most widely used screening test in the United States for the early detection of cervical cancer. Approximately 50 million Pap tests are performed annually in the United States, approximately 90% of which are from liquid PAP specimens.

Other APTIMA Products *APTIMA CT, APTIMA GC and APTIMA Trichomonas ASR.* To provide our customers with greater flexibility for their STD testing needs, we also have developed individual APTIMA assays to separately detect the presence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, which received FDA approval in December 2004 and March 2005, respectively. In October 2006, the FDA granted marketing clearance to run our

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stand-alone APTIMA assays for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* on the TIGRIS instrument. We have also developed ASRs to detect the parasite *Trichomonas vaginalis*. Trichomoniasis is one of the most common sexually transmitted diseases in the United States that mainly affects sexually active women. It is estimated by the CDC that 7.4 million new cases occur annually in the United States.

Clinical Diagnostic Products for the Detection of Viral Microorganisms

We produce qualitative diagnostic tests that can determine whether the virus is present, and quantitative tests that can determine the amount of the virus. These viral diagnostic assays include a qualitative HCV test, a qualitative HIV-1 RNA assay and an ASR for quantitative HCV testing, as set forth below, and currently are run on our semi-automated instruments incorporating components of our DTS instrument.

Product Line	Principal Technologies	Target Microorganism	FDA Clearance/Approval	Commercial Distribution
Qualitative HCV Assay	Target Capture, Transcription-Mediated Amplification of viral RNA, detection by Dual Kinetic Assay	HCV	November 2002 October 2006	Siemens Worldwide Gen-Probe U.S.
Qualitative HIV-1 RNA Assay	Target Capture, Transcription-Mediated Amplification of viral RNA, detection by Dual Kinetic Assay	HIV-1	October 2006	Gen-Probe Worldwide
ASR for Quantitative HCV Testing	Target Capture, Transcription-Mediated Amplification of viral RNA, detection by Hybridization Protection Assay	HCV	Not required	Siemens U.S.

Qualitative HCV Assay. We developed an amplified TMA assay for the qualitative detection of HCV based on the same technology used in our FDA-approved Procleix HIV-1/HCV assay for screening donated blood. Siemens currently distributes this assay under the trademark VERSANT in the United States and international markets under our collaboration agreement. We commenced distribution of this assay under our own APTIMA trademark in 2006.

Qualitative HIV-1 RNA Assay. In October 2006, the FDA approved our APTIMA HIV-1 RNA qualitative assay. The assay may be used as an aid in the diagnosis of HIV-1 infection, including acute and primary HIV-1 infection, and to confirm HIV-1 infection in individuals who repeatedly test positive for HIV-1 antibodies. The assay is the first FDA-approved qualitative nucleic acid test for these intended uses. We commenced distribution of this assay in December 2006.

ASR for Quantitative HCV Testing. We have also developed, through our collaboration with Siemens, ASRs to quantitatively determine the amount of HCV present in a sample. These ASRs and general purpose reagents currently are provided by Siemens to Quest Diagnostics Incorporated, a leading national diagnostics company.

Clinical Diagnostic Products for the Detection of Markers for Cancer

PROGENSA PCA3 Assay and ASRs. 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. DiagnoCure is the exclusive worldwide

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licensee for all diagnostic and therapeutic applications of the gene. We acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure in November 2003. We currently plan to modify our existing PCA3 assay for use with our investigational Panther instrument system. As of December 31, 2008, five clinical laboratory customers in the United States had completed validation of TMA assays for PCA3 and PSA using our ASRs and general purpose reagents.

APTIMA HPV Assay. We have developed an APTIMA HPV assay that is designed to detect 14 types of high-risk HPV associated with cervical cancer. More specifically, the assay is designed to detect two messenger RNAs that are made in higher amounts when HPV infections progress toward cervical cancer. According to the National Cancer Institute, cancer of the cervix affects more than 500,000 women worldwide each year. In March 2008, we commenced our U.S. clinical trials for our APTIMA HPV assay. In addition, in May 2008 we launched our APTIMA HPV assay in Europe.

Blood Screening Products

In 1996, the National Heart, Lung and Blood Institute of the 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.

Blood Screening Products

Product Line	Principal Technologies	Target Microorganism(s)	FDA Clearance/Approval	Commercial Distribution	
Procleix HIV-1/ HCV Assay	Target Capture, Transcription-Mediated Amplification of viral RNAs, detection by Dual Kinetic Assay	HIV-1 and HCV in donated blood, plasma, organs and tissues	February 2002	Novartis	Worldwide
Procleix WNV Assay	Target Capture, Transcription-Mediated Amplification of viral RNAs, detection by Dual Kinetic Assay	WNV in donated blood, plasma, organs and tissues	December 2005	Novartis	U.S.
Procleix Ultrio Assay	Target Capture, Transcription-Mediated Amplification of viral RNAs, detection by Dual Kinetic Assay	HIV-1, HCV and HBV in donated blood, plasma, organs and tissues	October 2006 (without blood screening claim for HBV) August 2008 (with blood screening claim for HBV)	Novartis	Worldwide

In 1998, in collaboration with Chiron (now Novartis), we were selected by The American Red Cross to provide an HIV-1/HCV assay for testing pooled blood samples under an Investigational New Drug application, or IND, filed with the FDA. The American Red Cross is the largest supplier of blood, plasma and tissue products in the United States.

The Gen-Probe/Novartis collaboration subsequently entered into similar arrangements with America s Blood Centers and American Independent Blood Centers. As a result of these and other implementations, we estimate that the Procleix HIV-1/HCV assay is currently utilized to screen over 80% of the United States donated blood supply.

The FDA approved our Biologic License Application, or BLA, for the Procleix HIV-1/HCV assay in February 2002. As a result of FDA approval, in the second quarter of 2002 Novartis began to sell the assay at commercial prices to United States customers, which resulted in our recognizing increased revenues. Regulations adopted by the European Union, or EU, require all imported in vitro diagnostic products, including our existing blood screening assays, to be registered and contain the CE mark. We received CE mark approval for our initial Procleix HIV-1/HCV blood screening assay in February 2003.

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As noted above, most blood collection centers currently screen donated blood by taking samples from individual donors and then conducting a nucleic acid test on the pooled samples. The Procleix HIV-1/HCV assay is performed on the eSAS instrument system, which provides sufficient throughput for screening pooled samples of donated blood.

In collaboration with Novartis, we have developed the Procleix Ultrio assay for the simultaneous detection of HIV-1, HCV and HBV, which we believe will further drive demand for our blood screening products. The test is distributed and marketed by Novartis. The Procleix Ultrio assay is designed to detect the presence of all known HIV-1 groups and subtypes and HCV and HBV genotypes in human plasma during the very early stages of infection, when those agents are present but cannot be detected by immunoassays. The HBV component of the assay has the potential to reduce the window period between infection and detection of HBV by up to 42% from the window period associated with new generation surface antigen tests. The Procleix Ultrio assay for use on our semi-automated instrument for export was CE marked in January 2004. In December 2004, the Procleix Ultrio assay on TIGRIS was CE marked, enabling us to begin commercialization of the Procleix Ultrio assay for use on the TIGRIS instrument in the European Economic Area, as well as in other parts of the world that accept the CE mark.

In October 2006 and May 2007, the FDA granted marketing approval for use of the Procleix Ultrio assay on eSAS and TIGRIS, respectively. The Procleix Ultrio assay was approved 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. The systems and assay also detect HBV in blood donations that are HBV-positive based on serology tests for HBV surface antigen and core antibodies. 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 on the TIGRIS system.

On December 1, 2005, the FDA granted marketing approval for the Procleix WNV assay on eSAS to screen donated human blood. The 510(k) clearance of eSAS for use with the WNV assay was granted prior to the assay s approval. In March 2007, the FDA approved the Procleix TIGRIS system to screen donated blood, organs and tissues for WNV using the Procleix WNV assay.

Products for Emerging Diagnostic and Industrial Testing Applications

With an aim to expand our offerings in the industrial testing market, we entered into an exclusive collaboration agreement with 3M in November 2006 to develop rapid molecular assays for the food testing industry. In addition, with an aim to expand our offerings in the clinical diagnostics market, we entered into a separate exclusive collaboration agreement with 3M in April 2007 to develop and commercialize rapid nucleic acid tests to detect certain dangerous HCAIs, such as methicillin-resistant *Staphylococcus aureus*. In November 2007, 3M informed us that it no longer intended to fund our collaboration to develop rapid molecular assays for the food testing industry. In June 2008, 3M discontinued our collaboration to develop rapid, molecular tests for HCAIs due to technical incompatibilities between our NAT technologies and 3M s proprietary microfluidics instrument platform. Prior to the termination of these collaborations, we achieved certain technical milestones with our prototype assays, entitling us to payments from 3M of $2.0 million relating to our prototype assays to enhance food safety and $2.7 million relating to our prototype assays for HCAIs. We are currently exploring other opportunities to commercialize our prototype assays in these fields.

In January 2008, Millipore commenced commercialization of the first MilliPROBE assay under our collaboration, which targets the bacterium *Pseudomonas aeruginosa* and is designed as an in-process, early warning system to provide faster, more effective detection of *Pseudomonas aeruginosa* in purified water used during drug production. The assay is designed to ensure a higher degree of water quality throughout manufacturing processes where the contaminant can be a serious quality and safety concern. We believe faster detection will enable biopharmaceutical manufacturers to reduce downstream processing risks, optimize product yields and improve final product quality.

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.

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Historically, we have provided our instrumentation to laboratories 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 amounts we charge for our diagnostic assays. We have implemented multi-year sales contracts that have an equipment factor included in them. 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.

TIGRIS Instrument System

We have developed the TIGRIS instrument system, or TIGRIS instrument, which we believe is the first high-throughput instrument to automate NAT testing, for use in both the clinical diagnostic and blood screening markets. The TIGRIS instrument integrates and automates all of the steps associated with our latest amplified NAT assays, including sample preparation, sample processing, amplification and detection. It has the ability to process approximately 500 samples in an eight-hour shift and up to 1,000 samples in about 14 hours. In addition, two TIGRIS instruments can be operated under the supervision of a single lab technician.

The TIGRIS instrument is designed to reduce the time, labor costs, risk of contamination and complexity associated with performing NAT assays and blood screening. The throughput of the TIGRIS instrument is sufficient to allow high volume testing of individual blood donations, rather than pooled donor samples. The TIGRIS instrument is being utilized in numerous blood banks, as well as clinical diagnostic laboratories, which we believe is helping to drive our growth in the STD testing market. We intend to develop additional NAT assays that can be performed on the TIGRIS instrument.

DTS 400, 800 and 1600 Instruments

Laboratories need nucleic acid testing solutions that are accurate, efficient and economical. To meet this demand, we have developed the family of DTS instruments. The DTS family of instruments uses direct tube sampling (DTS) technology and an exclusive penetrable cap on the sample collection tube to minimize contamination and achieve safer, more convenient, sample removal. DTS simplifies sample transport, minimizes handling and greatly reduces laboratory cross-contamination. These instruments include the DTS 400, DTS 800 and DTS 1600. This is a full line of semi-automated solutions for low, medium and high-volume laboratories to be used with our latest generation of NAT assays, including the APTIMA Combo 2 assay. The instrument platforms can also be adapted to perform the PACE family of assays, GASDirect Test, and AccuProbe Group B Strep assay.

Novartis markets a version of the DTS 1600 instruments, also known as the Procleix System or eSAS, for use in blood screening under the Procleix trademark. The version of the DTS instruments that Novartis markets has received FDA approval and foreign governmental approval in the countries where our blood screening products are sold. Siemens markets systems comprised of components of the DTS instruments for HCV clinical diagnostic assays.

Luminometers

Our LEADER series of luminometers, designed in conjunction with MGM Instruments, Inc., are used with our PACE, AccuProbe and APTIMA products. Utilizing advanced chemiluminescent detection, our luminometers provide high sensitivity, speed, accuracy and ease-of-use. Currently, there is an installed base of over 2,100 of our luminometers worldwide. The LEADER series can accommodate the throughput needs of low-volume testing laboratories. We have no firm, long-term commitments from MGM Instruments to supply products to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order. No FDA or foreign governmental approval is required to sell our current LEADER series of luminometers in the clinical diagnostic market.

Panther Instrument System

We are currently developing a new automated 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, we authorized Stratec Biomedical Systems AG, or Stratec, to commence its Phase 2

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development activities pursuant to our development agreement. Stratec is providing services for the design and development of the Panther instrument system, as well as the production of prototype, validation, pre-production and production instruments.

CUDA Instrument System

Under our license agreement with Qualigen, we have conducted feasibility research and development for a closed unit dose assay, or CUDA, instrument and an associated reagent pouch. We believe that a point-of-sample-collection instrument, such as the CUDA instrument, may offer potential advantages in industrial testing and other applications. We are currently evaluating market opportunities, customer requirements and instrument performance based on our research and development activities to date.

Marketing and Sales

We market our products for the clinical diagnostics market to laboratories in the United States and Canada through our direct sales force. We also market our APTIMA and PROGENSA PCA3 products in certain European countries 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, 2008, our direct sales force consisted of a staff of 39 sales employees. We also support our sales efforts through a staff of 47 field technical employees. Our sales representatives have an average of approximately 17 years of overall sales experience, with an average of approximately 11 years focused on sales of NAT products. Sales representatives principally focus on large accounts, including reference laboratories, public health institutions and hospitals throughout North America and certain European countries. We educate our sales representatives on the technical, clinical and economic merits of our products. We use sales meetings, technical on-line sales training and in-the-field training to ensure our sales representatives are properly informed about all areas of our product lines and selling processes. Our blood screening products are marketed and distributed by Novartis.

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 concentrate our selling efforts on the management teams of laboratories and hospitals. Our sales representatives are able to recommend the appropriate business solution to meet the needs of our customers by presenting multiple NAT technology and instrumentation options. Sales representatives are trained to find new product opportunities, offer diagnostic solutions to address unmet customer needs, and provide comprehensive after-sale product support. In addition, our field technical support group provides training and ongoing technical support for all of our NAT products.

Distributors

We have an agreement with 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 Rebio Gen. 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.

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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 48% of our total revenues in 2008 and 45% of our total revenues in 2007. 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 2008. Various state and city public health agencies accounted for an aggregate of 8% and 9%, respectively, of our total revenues in 2008 and 2007. Although state and city public health agencies are legally independent of each other, we believe they tend to act similarly with respect to their purchasing decisions.

Corporate Collaborations and Strategic Arrangements

Agreement with Novartis (formerly Chiron Corporation)

In June 1998, we entered into a collaboration agreement with Chiron Corporation (now Novartis), or the 1998 Agreement, to develop and market NAT-based products for the blood screening and clinical diagnostic markets. Chiron subsequently assigned the clinical diagnostics portion of the agreement to Bayer (which, in turn, assigned the clinical diagnostics portion of the agreement to Siemens). The Gen-Probe/Novartis alliance initially developed and is manufacturing and marketing the combination HIV-1/HCV assay for qualitative screening of blood and blood products under the Procleix name. Additional blood screening assays, such as the Procleix Ultrio assay and the WNV assay, have been developed through the collaboration and are discussed elsewhere in this Annual Report. In the event that any third-party technology is needed to continue development under the collaboration agreement, costs for obtaining such third-party technology will be allocated between the parties.

In January 2009, we entered into an agreement with Novartis to amend the 1998 Agreement, effective as of January 1, 2009, which we refer to herein as Amendment No. 11. Amendment No. 11 extends to June 30, 2025 the term of the parties blood screening collaboration under the 1998 Agreement. The 1998 Agreement was previously scheduled to expire by its terms in 2013. The collaboration agreement can be terminated by either party prior to the expiration of its term if the other party materially breaches the collaboration agreement and does not cure the breach following 90 days notice, or if the other party becomes insolvent or declares bankruptcy.

The 1998 Agreement provided that we were solely responsible for manufacturing costs incurred in connection with the collaboration, while Novartis was responsible for sales and marketing expenses associated with the collaboration. Amendment No. 11 provides that, effective January 1, 2009, we will recover 50% of our costs of goods sold incurred in connection with the collaboration. In addition, we will receive a percentage of the blood screening assay revenue generated under the collaboration, as described in the next paragraph.

The 1998 Agreement provided that the parties share revenue from the sale of blood screening assays under the collaboration. Under the terms of the 1998 Agreement, as previously amended, our share of revenue from any assay that included a test for HCV was 45.75%. Amendment No. 11 modifies our share of such revenue, initially reducing it to 44% for 2009. Our share of blood screening assay revenue increases in subsequent years as follows: 2010-2011, 46%; 2012-2013, 47%; 2014, 48%; and 2015, 50%. Our share of blood screening assay revenue is fixed at 50% from January 1, 2015 though the remainder of the amended term of the agreement. Under Amendment No. 11, our share of blood screening assay revenue from any assay that does not test for HCV remains at 50%. As discussed above, we are entitled to our designated percentage of revenue from the sale of blood screening assays as well as the recovery of 50% of our costs of goods sold. Amendment No. 11 also provides that Novartis will reduce the amount of time between product sales and payment of our share of blood screening assay revenue from 45 days to 30 days.

As part of Amendment No. 11, the parties have agreed, and Novartis has agreed to provide certain funding, to customize our Panther instrument, a fully automated molecular testing platform now in development, for use in the blood screening market. Novartis has also agreed to pay us a milestone payment upon the first commercial sale of the Panther instrument. The parties will equally share 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.

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All rights and title to inventions discovered under the collaboration agreement belong to the party who developed the invention, or to both parties, if both parties developed the invention. However, if one party uses confidential information relating to the core technology of the other party to develop an invention that improves on, and whose use would infringe on, the core technology of the other party, then the other party will have the exclusive option to acquire all rights and title to the invention on commercially reasonable terms, except in certain situations where the invention will be jointly owned.

In January 2004, we began United States clinical trials of the Procleix Ultrio assay on the TIGRIS instrument, triggering a $6.5 million contract milestone payment from Novartis that we recorded during the first quarter of 2004. During January 2004, the Procleix Ultrio assay, with our semi-automated instrument, was CE marked, which permitted Novartis to launch the product in the European Economic Area. In December 2004, the Procleix Ultrio assay on TIGRIS was CE marked enabling the commercialization of the Procleix TIGRIS system in the European Economic Area, as well as in other parts of the world that accept the CE mark. In October 2006 and May 2007, the FDA granted marketing approval for use of the Procleix Ultrio assay on 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 screen donated blood, plasma, organs and tissues for HBV in addition to HCV and HIV-1 and, as a result, we received from Novartis a $10.0 million milestone payment in the third quarter of 2008.

From inception through December 31, 2008, we recognized a total of $1.1 billion in revenue under this collaboration agreement and had recorded $3.0 million in deferred license revenues as of December 31, 2008.

Agreement with Siemens Healthcare Diagnostics, Inc. (formerly Bayer Corporation)

In 1998, following the execution of our collaboration agreement with Chiron Corporation (now Novartis), Chiron assigned the clinical diagnostic portion of the agreement to Bayer. On December 31, 2006, Bayer completed the sale of its diagnostics division to Siemens AG and assigned the clinical diagnostics portion of the agreement to Siemens Healthcare Diagnostics, Inc. As a result of the settlement agreement we entered into with Bayer in August 2006, or the Settlement Agreement, which has also been assigned to Siemens and is discussed below, the collaboration agreement has been terminated, except as to quantitative ASRs and qualitative assays for HCV as discussed below.

Under the terms of the 1998 Agreement, Siemens is obligated to pay us a combination of transfer prices and royalties on product sales with respect to the quantitative ASRs and qualitative assays for HCV. From inception through December 31, 2008, we recognized a total of $49.1 million in revenue under our collaboration agreement with Siemens, including $18.4 million in revenue during 2008, $16.4 million of which as a one-time royalty payment we received in January 2008 under the Settlement Agreement described below.

In November 2002, we initiated an arbitration proceeding against Bayer in connection with our collaboration. In August 2006, we entered into the Settlement Agreement with Bayer, resolving all litigation and arbitration proceedings between the parties. As part of the Settlement Agreement, the parties submitted a stipulated final award in the original November 2002 arbitration proceeding we filed against Bayer, adopting the arbitrator s prior interim and supplemental awards, except that Bayer was no longer obligated to reimburse us $2.0 million for legal expenses. The arbitrator s June 5, 2005 Interim Award determined that we are entitled to a co-exclusive right to distribute qualitative TMA assays to detect HCV and HIV-1 for the remaining term of the collaboration agreement between the parties on our DTS 400, 800, and 1600 instrument systems. The arbitrator also determined that the collaboration agreement should be terminated, as we requested, except as to the qualitative HCV assays and as to quantitative ASRs for HCV. Siemens retains the co-exclusive right to distribute the qualitative HCV tests and the exclusive right to distribute the quantitative HCV ASR. As a result of the termination of the agreement other than for these HCV tests, we re-acquired the right to develop and market future viral assays that had been previously reserved for Siemens. The arbitrator s

March 3, 2006 supplemental award determined that we are not obligated to pay an initial license fee in connection with the sale of the qualitative HIV-1 and HCV assays and that we will be required to pay running sales royalties, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents. Pursuant to the Settlement Agreement, Bayer paid us an initial license fee of $5.0 million in August 2006, an additional $10.3 million as a one-time royalty in January 2007 and a final one-time royalty

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payment of $16.4 million in January 2008. As a result of these payments, Bayer s rights to the patents subject to the Settlement Agreement are fully paid-up and royalty free.

Pursuant to the Settlement Agreement, we have an option to extend the term of the license granted in the arbitration for qualitative HIV-1 and HCV assays, so that the license would run through the life of the relevant HIV-1 and HCV patents. The option also permits us to elect to extend the license to future instrument systems (but not to the TIGRIS instrument). We are required to exercise the option prior to expiration of the existing license in October 2010 and, if exercised, pay a $1.0 million fee.

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. We plan to use these oligonucleotides in 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 patent rights relevant to the agreement and may be terminated by either party upon a material breach of the agreement by the other party that is not cured following 60 days written notice and in certain other limited circumstances.

In December 2006, Digene Corporation, or Digene, filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution of the American Arbitration Association in New York, or ICDR. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and seeks a determination that the supply and purchase agreement is null and void. On July 13, 2007, the ICDR arbitrators granted our petition to join the arbitration. On August 27, 2007, Digene filed an amended arbitration demand and asserted a claim against us for tortious interference with the cross-license agreement. The arbitration hearing in this matter commenced October 27, 2008 and the presentation of evidence concluded November 10, 2008. In December 2008 and January 2009, the parties filed post-hearing briefs and closing arguments were presented on January 30, 2009.

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.

Collaboration Agreement with GEI

In July 2005, we entered into a collaboration agreement with GEI to develop, manufacture and commercialize NAT products designed to detect the unique genetic sequences of microorganisms for GEI s exclusive use or sale in selected water testing applications. Under the terms of the agreement, we will be primarily responsible for assay development and manufacturing, while GEI will manage worldwide commercialization of any products resulting from the collaboration. The agreement terminates on the later of the date that is 10 years after the first commercial

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sale or use of the first assay developed under the agreement and five years after the first commercial sale or use of the last assay launched prior to the 10 year period specified above. In addition, either party may terminate the agreement upon a breach of a material provision of the agreement by the other party that is not cured following 90 days written notice and in certain other limited circumstances.

Collaboration Agreement with Millipore

In August 2005, we entered into a collaboration agreement with Millipore to develop, manufacture and commercialize NAT products for rapid microbiological and viral monitoring for Millipore s exclusive use or sale in process monitoring in the biotechnology and pharmaceutical manufacturing industries. Under the terms of the agreement, we will be primarily responsible for assay development and manufacturing, while Millipore will manage worldwide commercialization of any products resulting from the collaboration. The agreement terminates upon the expiration of any two-year period during which there has been no development work conducted under the agreement or no first commercial sale of a product developed under the agreement. In addition, either party may terminate the agreement upon a material breach of the agreement by the other party that is not cured following 120 days written notice and in certain other limited circumstances. Millipore launched the first product under our collaboration in January 2008.

Agreements with Molecular Profiling Institute, Inc.

In October 2005, we entered into agreements with Molecular Profiling Institute, Inc., or Molecular Profiling, to accelerate market development for our cancer diagnostics. Under the terms of the agreements, Molecular Profiling has agreed to validate, commercialize and undertake market development activities for up to four of our products, starting with our ASRs to detect PCA3. The agreements may be terminated, with required notice, upon a material breach and in certain other limited circumstances. In addition, we purchased $2.5 million of Series B Preferred Stock of Molecular Profiling. Molecular Profiling was acquired in January 2008 and we received approximately $4.1 million in cash for our shares and as a result realized approximately $1.6 million in gain for our investment. Our commercial agreements with Molecular Profiling (now Caris MPI, Inc.) remain in effect.

Agreements with Stratec

In November 2006, we entered into a development agreement and supply agreement with 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, that will cost approximately $10.2 million in the aggregate if we elect to purchase the number of each instrument type we currently expect to purchase. We will also purchase production tooling from Stratec at a cost of approximately $1.2 million.

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 are 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.

Technology Licenses

Licenses of Our Technology We Have Granted to Other Companies

Agreements with bioMérieux. In May 1997, we entered into collaborative research agreements with bioMérieux, which created a worldwide relationship between bioMérieux and us.

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In August 2000, we entered into amended agreements with bioMérieux that transitioned the relationship from a collaborative arrangement to two royalty-bearing license agreements covering a semi-automated instrument and associated probe assays and an advanced fully-automated instrument and probe assays, both for the diagnosis of infectious diseases and detection of food pathogens. In September 2004, we entered into a termination agreement with bioMérieux, which terminated one of the August 2000 license agreements. Pursuant to the termination agreement, bioMérieux paid us an aggregate of approximately $1.6 million to conclude certain outstanding royalty and other obligations under the terminated license agreement. Further, we paid $1.0 million to bioMérieux to gain access to bioMérieux s intellectual property for detecting genetic mutations that predispose people to blood clotting disorders. In February 2006, bioMérieux terminated the second of the two August 2000 license agreements. In December 2006, bioMérieux paid us $0.4 million in settlement of a minimum annual royalty obligation under this agreement, thereby fulfilling its final obligations under the terminated license.

In September 2004, at the same time we entered into the first termination agreement referenced above, we also entered into non-exclusive licensing agreements with bioMérieux and its affiliates that provide bioMérieux s affiliates with options to access our rRNA technologies for certain uses. We refer to these agreements as the Easy Q agreement and the GeneXpert agreement. Pursuant to the terms of these agreements, bioMérieux s affiliates paid us an aggregate of $0.3 million for limited non-exclusive, non-transferable, research licenses, without the right to grant sublicenses except to affiliates, and non-exclusive, non-transferable options for licenses to develop diagnostic products for certain disease targets using our patented ribosomal RNA technologies. The first of these options was exercised by bioMérieux s affiliates payment to us of $4.5 million in January 2005. In December 2005, bioMérieux s affiliates exercised a second option and paid us $2.1 million. We recognized an aggregate of $3.9 million as license revenue in 2005 as a result of these payments. bioMérieux s affiliates had an option to pay $1.0 million by December 31, 2006 for access to additional targets, but did not exercise this option. As a result of the expiration of this option period, we recognized a total of $3.0 million as revenue in 2006 for amounts previously paid by bioMérieux but deferred.

Under each license, we will receive royalties on the net sale of any products bioMérieux and its affiliates develop using our intellectual property. The resulting license agreements terminate upon the expiration of the last to expire patent covered by the agreement. In the event of a change in control with respect to bioMérieux or its affiliates, we have the right to terminate these agreements, and the respective licenses granted to bioMérieux s affiliates thereunder, upon 60 days prior written notice to bioMérieux delivered within six months of the date of the change in control. The respective obligations of bioMérieux s affiliates under the agreements is guaranteed by bioMérieux SA, the parent company of the bioMérieux affiliates that are parties to the agreements.

License Agreement with Rebio Gen. In July 2001, we entered into a license agreement with Chugai Diagnostics Science Co., Ltd., a subsidiary of our parent corporation at that time. In September 2002, Chugai Diagnostics Science Co., Ltd. was acquired by Fujirebio, which re-named the company Rebio Gen, Inc. The license agreement has an initial term of 10 years, with automatic renewal for consecutive one year terms unless one party gives the other party notice 90 days prior to the end of the current term. Under the terms of this agreement, Rebio Gen has a non-exclusive license for Japan in the field of human clinical diagnostics to various of our proprietary technologies, including TMA and HPA technology. All rights and title to any discovery, invention or improvement made by Rebio Gen as a result of access to our patent rights licensed under the agreement belong solely to Rebio Gen. We received a license fee and a royalty payment for sales made prior to the effective date of the agreement and will receive royalty payments from products incorporating the licensed technology, including those developed and commercialized by Rebio Gen, until the expiration of our patents incorporated in these products, which is expected to occur in December 2020. From inception through December 31, 2008, we recognized a total of $3.9 million in revenue under this agreement, including $0.4 million in revenue during 2008. This agreement may be terminated by either party upon breach of the agreement that is not cured following 60 days written notice. We also received rights to distribute outside of Japan any products that may be developed by Rebio Gen under the license.

Non-Exclusive License with Becton Dickinson and Company. In September 1995, we granted Becton Dickinson a non-exclusive worldwide license to make, have made, use, sell and import products that utilize rRNA for the diagnosis of vaginosis and vaginitis in humans. Becton Dickinson paid us an up-front license fee and has agreed to pay us royalties for the life of the licensed patents. From inception through December 31, 2008, we recognized a total of $8.3 million in revenue under this agreement, including $1.7 million in revenue during 2008.

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Becton Dickinson s obligations to make royalty payments under this agreement terminate when the patents that are the subject of this agreement expire, which is expected to occur in March 2015. Becton Dickinson can terminate the agreement at any time on 30-days prior written notice.

Cross Licensing Agreements with Tosoh. In December 2003, we entered into agreements with Tosoh Corporation to cross-license intellectual property covering certain NAT technologies. The licenses, which were effective January 1, 2004, cover products in clinical diagnostics and other related fields. Under the agreements, Tosoh received non-exclusive rights to our proprietary TMA and rRNA technologies in exchange for two payments to us totaling $7.0 million in 2004. We also received a $1.0 million payment from Tosoh in 2006 as the terms of our license agreement were expanded in connection with the Bayer settlement. Additionally, Tosoh will pay us royalties on worldwide sales of any products that employ our technologies licensed by Tosoh. We will gain access, in exchange for royalty payments to Tosoh, to Tosoh s patented TRC amplification and INAF detection technologies for use with our real time TMA. The agreements terminate at various times commencing in July 2010 through the expiration of the last to expire patents subject to the agreements and may be terminated by either party upon material breach of the agreement by the other party that is not cured following 60 days written notice.

Licenses We Have Obtained to Third-Party Technology

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, 2008, we incurred a total of $11.7 million in expenses under this agreement, including $3.0 million in expenses during 2008. 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.

Non-Assertion Agreement with Organon Teknika B.V. In February 1997, we entered into a non-assertion agreement with Organon Teknika. Both parties possessed certain rights regarding transcription-based amplification methods. The agreement allows both parties to practice their respective amplification methods with immunity from legal action from the other party for actually or allegedly infringing each other s patent rights. The agreement terminates upon the expiration of the last of the patent rights that are subject to the agreement, which is expected to occur in July 2017. This agreement also may be terminated by Organon Teknika upon a material breach of the agreement by us that is not cured following 90 days written notice. In July 2001, Organon Teknika merged with bioMérieux.

Non-Exclusive License from Vysis, Inc. In June 1999, we obtained a non-exclusive license from Vysis granting us rights under certain patents covering methods that combine target capture technology with certain nucleic acid amplification methods. We paid a license fee and became obligated to make royalty payments to Vysis based on sales of products incorporating the licensed technology. The agreement terminates upon the expiration of the last of the patent rights that are subject to the agreement, which is expected to occur in July 2015. In December 2001, Vysis was acquired by Abbott Laboratories, Inc., one of our principal competitors.

In September 2004, following litigation between the parties concerning the scope, validity and enforceability of the licensed patents, we entered into a settlement agreement and an amendment to the non-exclusive license agreement. Under the settlement agreement, we agreed to terminate the litigation and pay Abbott an aggregate of $22.5 million. This aggregate amount included $20.5 million for a fully paid up license to eliminate all of our future royalty

obligations under the license, and $2.0 million for a fully paid-up, royalty-free license in additional fields under the licensed patents. The paid-up license now covers current and future products in the field of infectious diseases and all other fields. Novartis reimbursed us $5.5 million of the $20.5 million allocated to the cost of the fully paid-up license for the current field, commensurate with its obligation to reimburse us for a portion of the royalties due on the sale of blood screening products.

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Non-Exclusive License with the Public Health Research Institute of The City of New York, Inc. In June 1997, we entered into a royalty bearing non-exclusive license with the Public Health Research Institute of The City of New York, or PHRI, to utilize PHRI s fluorescently labeled NAT technology. Under this agreement, which was amended in February 2006, we have worldwide rights to develop, use and market kits in the field of human *in vitro* diagnostics, food testing, environmental testing and industrial microbiology testing. We paid a license fee and agreed to make milestone payments and annual license fee payments, and to pay royalties on the net sales price of products incorporating the licensed technology, subject to a minimum annual royalty fee and a reduction in the royalties based on the quantity of sales. From inception through December 31, 2008, we incurred a total of $2.2 million in license fees and $0.4 million in milestone payments under this agreement. We anticipate that we will pay up to an additional $1.0 million in milestone payments over the remaining term of the agreement. The agreement terminates upon the expiration of the last of the patent rights that are subject to this agreement, which is expected to occur in April 2017. The agreement may be terminated by PHRI upon a material breach of the agreement that is not cured following 30 days written notice, or by us for any reason following 30 days written notice.

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 a gene called PCA3 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 of $3.0 million and paid additional fees and contract development payments of $7.5 million over the three years following execution of the contract. 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.

The agreement provides that we may lose exclusivity with respect to the licensed PCA3 marker if we fail to diligently develop the collaborative diagnostic test. This 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. We may terminate the agreement for any reason following 30 days written notice to DiagnoCure, or following 30 days written notice to DiagnoCure in the event a licensed product fails to produce a certain level of results in any clinical trial.

In May 2006, we amended our license and collaboration agreement with DiagnoCure. Pursuant to the terms of the amendment (i) we granted exclusive rights to DiagnoCure to develop *in vivo* products for the detection or measurement of PCA3 as a marker for the diagnosis, monitoring or prognosis of prostate cancer, (ii) we granted co-exclusive rights to DiagnoCure to develop fluorescence *in situ* hybridization products for the detection or measurement of PCA3 as a marker for the diagnosis, monitoring or prognosis of prostate cancer, (iii) DiagnoCure agreed to undertake over a twelve-month period the validation of genetic markers that we acquired under our license agreement with Corixa Corporation, or Corixa, and we agreed to make monthly payments to DiagnoCure for these services, and (iv) we agreed to a new regulatory timeline regarding our development obligations for an *in vitro* diagnostic assay for PCA3. We currently plan to modify our existing PCA3 assay for use with our investigational Panther instrument system.

Exclusive License Option Agreement with Qualigen, Inc. In November 2004, we entered into an agreement with Qualigen under which we had an exclusive option to develop and commercialize a NAT instrument designed for use at the point of sample collection based on Qualigen s FDA-approved FastPack immunoassay system. If successfully developed, the portable instrument would use our NAT technology to detect, at the point of sample collection, the presence of harmful microorganisms, genetic mutations and other markers of diseases. Under the terms of the agreement, we paid Qualigen $1.0 million for an 18-month option to license, on an exclusive worldwide basis,

Qualigen s technology to develop NAT assays for the clinical diagnostics, blood screening and industrial fields. We exercised the option in April 2006 and in conjunction therewith purchased shares of Qualigen preferred stock convertible into approximately 19.5% of Qualigen s then outstanding fully diluted common shares. The cost of acquiring this equity interest was $7.0 million. In addition, we may pay Qualigen up to $3.0 million in license fees based on development milestones, as well as royalties on any eventual product sales. Either party may

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terminate the agreement for cause by written notice to the other party of an uncured material breach by the other party or upon certain insolvency events.

Exclusive License from AdnaGen AG. In December 2004, we entered into a license agreement with AdnaGen AG to license from AdnaGen cell capture technology for use in our molecular diagnostic tests to detect prostate and other cancers. Under the terms of the agreement, we recorded license fees of $1.75 million ($0.75 million in 2006 and $1.0 million in 2004). We also agreed to pay AdnaGen up to three milestone payments totaling an additional $2.25 million based on the occurrence of certain clinical, regulatory and/or commercial events. Further, we agreed to pay AdnaGen royalties on net sales of any products developed by us using AdnaGen s technology. Additionally, we were granted options through June 30, 2006, which term was later extended, to obtain exclusive licenses to use AdnaGen s technology in molecular diagnostic tests for kidney, ovarian and cervical cancers. We did not exercise these options. We retain a three-year right of first negotiation to negotiate with AdnaGen on exclusive rights to molecular diagnostic tests for breast, colon and lung cancers in the event that AdnaGen proposes to grant to any third party a license to AdnaGen technology for use to detect any of these cancers. The agreement will expire on the expiration of our obligation to pay royalties to AdnaGen under the agreement, which obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed technology. We may terminate the agreement in our sole discretion upon 30 days prior written notice to AdnaGen, provided we have made any outstanding payments required under the agreement. Either party may terminate the agreement for cause by written notice to the other party of an uncured material breach by the other party or if the other party is unable to pay its debts or enters into compulsory or voluntary liquidation.

License Agreement with Corixa Corporation. In January 2005, we entered into a license agreement with Corixa, which was later acquired by GSK, pursuant to which we received the right to develop and commercialize molecular diagnostic tests for multiple potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancer. Pursuant to the terms of the agreement, we paid Corixa an initial access license fee of $1.6 million, and an additional $1.6 million in each of February 2006 and January 2007. Pursuant to the agreement, we also agreed to pay Corixa milestone payments totaling an additional $2.0 million on a product-by-product basis based on the occurrence of certain regulatory and/or commercial events. We also agreed to pay Corixa additional milestone payments and royalties on net sales of any products developed by us using Corixa s technology. The agreement will expire on the expiration of our obligation to pay royalties to Corixa under the agreement, which obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed patent rights. We may terminate the agreement in our sole discretion upon 30 days prior written notice to Corixa, provided we have made any outstanding payments due under the agreement. Either party may terminate the agreement for cause by written notice to the other party of an uncured material breach by the other party or if the other party is unable to pay its debts or enters into compulsory or voluntary liquidation.

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. In May 2006, pursuant to the terms of this agreement, we paid a license fee of $0.5 million to the University. We also agreed to pay royalties on eventual product sales, as well as development milestones. In addition, we will 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.

Patents and Proprietary Rights

To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade secrets 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

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the majority of our anticipated customer base. As of December 31, 2008, we owned more than 470 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.

United States utility patents issued from applications filed prior to June 8, 1995 have a term of the longer of 20 years from the earliest priority date or 17 years from issue. United States utility patents issued from applications filed on or after June 8, 1995 have a term of 20 years from the earlier of the application filing date or earlier claimed priority date of a regular application. 108 of our current United States utility patents issued from applications filed prior to June 8, 1995. 135 of our United States utility patents issued from applications filed on or after June 8, 1995. We have four United States design patents that issued from applications filed on or after June 8, 1995 and have a term of 14 years from the date of issue. Patents in most foreign countries have a term of 20 years from the date of filing of the patent application. Because the time from filing to issuance of patent applications is often several years, this process may result in a shortened period of patent protection, which may adversely affect our ability to exclude competitors from our markets. The last of our currently issued patents will expire by December 8, 2025. 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 any novel and newly developed products and technologies.

On January 9, 2004, our basic patents covering detection of organisms using probes to ribosomal nucleic acid (the Kohne patents) expired in countries outside North America. While we have additional patents relating to ribosomal nucleic acid detection that remain in effect outside North America, these patents may not provide sufficiently broad protection to prevent competitors from selling products based on ribosomal nucleic acid detection in markets outside North America. In the United States, the last-to-expire of the Kohne patents remains in effect until March 3, 2015.

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, diagnostic, health care, pharmaceutical and biotechnology companies. Our major competitors in the NAT market include Roche, Abbott Laboratories, through its subsidiary Abbott Molecular Inc. or, collectively, Abbott, Becton Dickinson, Siemens 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.

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.

In the markets for clinical diagnostic products, a number of competitors, including Roche, Abbott, Becton Dickinson, Siemens and bioMérieux, compete with us for product sales, primarily on the basis of technology, quality, reputation,

accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. Our competitors may be in better position 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 than we are. In the areas of NAT diagnostics for STDs, Roche and Becton Dickinson currently have FDA-approved tests for chlamydia infections

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and gonorrhea utilizing amplification technology. Although we believe that the APTIMA Combo 2 test has commercial advantages over the competing tests from Roche, Becton Dickinson and others, these competitors and potential competitors may be able to develop technologies that are as effective as, or more effective, or easier to interpret or less expensive than, those offered by us, which would render our products uncompetitive or obsolete.

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, our primary competitor is Roche, which received FDA approval of its PCR-based NAT tests for blood screening in December 2002. We also compete with assays developed internally by blood collection centers and laboratories based on PCR technology, an HCV antigen assay marketed by Ortho Clinical Diagnostics, a subsidiary of Johnson & Johnson, and immunoassay products from Abbott and Siemens. In the future, our blood screening products may compete with viral inactivation or reduction technologies and blood substitutes.

Novartis, with whom we have a collaboration agreement for our blood screening products, 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 that 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.

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 product kits 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. If we modify our products that already have received FDA clearance, the FDA may require us to submit a separate 510(k), a special 510(k) or a premarket approval application, or PMA, for the modified product before we are permitted to market it in the United States. In addition, if we develop products in the future that are not considered to be substantially equivalent to a legally marketed device, we will be required to obtain FDA approval by submitting a PMA.

By regulation, the FDA is required to respond to a 510(k) within 90 days of submission of the application. As a practical matter, final clearance often takes longer. The FDA may require further information, including additional clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent, the device sponsor must then fulfill much more rigorous premarketing requirements or re-submit a new 510(k) with additional data.

The PMA process is more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, including data from preclinical studies, human clinical trials and existing research material, and must contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. The FDA has 180 days to review a filed PMA application, although the

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review of an application more often occurs over a significantly longer period of time, up to several years. In approving a PMA application or clearing a 510(k) application, the FDA also may require some form of post-market surveillance, whereby the manufacturer follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. Our diagnostic assays for HCV and tuberculosis are examples of successful PMA applications.

When FDA approval of a clinical diagnostic device requires human clinical trials, and if the device presents a significant risk (as defined by the FDA) to human health, the device sponsor is required to file an investigational device exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. If the device is considered a non-significant risk, IDE submission to the FDA is not required. Instead, only approval from the Institutional Review Board overseeing the clinical trial is required.

Clinical trials must be conducted in accordance with Good Clinical Practice under protocols generally submitted to the FDA. Our clinical department has comprehensive experience with clinical trials of NAT products.

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 Services 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 following:

- completion of preclinical testing;
- submission of an IND, which must become effective before clinical trials may begin; and
- 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 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 patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have exclusive rights to exploit them.

The results of product development and human studies are submitted to the FDA as part of each BLA. The BLA also must contain extensive manufacturing information. The FDA may approve or disapprove a BLA if applicable FDA regulatory criteria are not satisfied or it may require additional clinical data. If approved, the FDA may withdraw a product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies

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to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers.

Satisfaction of FDA pre-market approval requirements for biologics can take several years and the actual time required may vary substantially based on the type, complexity and novelty of the product or disease. In general, government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote biologics, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has broad enforcement authority under the FFDCA, and failure to abide by applicable FDA regulations can result in penalties including the issuance of a warning letter directing the entity to correct deviations from FDA standards, 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 performance claims for the product and may only sell the product to clinical laboratories that are qualified to run high complexity tests under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. Each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory validated assay. We currently offer 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 (ISO) certification, 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 upon us. In addition, in the course of our business, we handle, store and dispose of chemicals. The environmental laws and regulations applicable to our operations include provisions that regulate the discharge of materials in the environment. Usually these environmental laws and regulations impose strict liability, rendering a person liable without regard to negligence or fault on the part of, or conditions caused by, others. We have not been required to expend material amounts in connection with our efforts to comply with environmental requirements. Because the requirements imposed by these laws and regulations frequently change,

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we are unable to predict the cost of compliance with these requirements in the future, or the effect of these laws on our capital expenditures, results of operations or competitive positions.

Manufacturing and Raw Materials

We have two state-of-the-art manufacturing facilities in the United States. Our Mira Mesa manufacturing facility in San Diego, California is dedicated to producing our clinical diagnostic products. In 1999, we completed our manufacturing facility in Rancho Bernardo 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. We built this facility with the capability to expand its operations to include production of additional assays for the blood screening market. We believe this facility has the capacity to produce sufficient tests to satisfy current and foreseeable demand for these blood screening assays. On February 1, 2008, we completed the purchase of this facility for $15.7 million. We also have a manufacturing facility in Cardiff, United Kingdom. We believe that our existing manufacturing facilities provide us with capacity to meet the needs of our currently anticipated growth.

We store our finished products at our warehouses in our manufacturing facilities. Some of our products must be stored in industrial refrigeration or freezer units that are on site. We ship our products under ambient, refrigerated or frozen conditions, as necessary, through third-party service providers.

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, and MGM Instruments is the only manufacturer of our LEADER series of luminometers. 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.

We use a diverse and broad range of raw materials in the design, development and manufacture of our products. Although we produce some of our materials on site at our manufacturing facilities, we purchase most of the materials and components used to manufacture our products from external suppliers. In addition, we purchase many key raw materials from single source suppliers. For example, our current supplier of key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is the Roche Molecular Biochemicals Division of Roche Diagnostics GmbH, an affiliate of Roche Molecular Diagnostics, which is one of our primary competitors. In addition, we have entered into a supply and purchase agreement with F. Hoffmann-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc. for the manufacture and supply of probes for HPV. We work closely with our suppliers to assure continuity of supply while maintaining high quality and reliability. Although we generally consider and identify alternative suppliers, we do not typically pursue alternative sources due to the strength of our existing supplier relationships.

Quality Systems

We have implemented modern quality systems and concepts throughout our organization. Our regulatory and quality assurance departments supervise our quality systems and are responsible for assuring compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies, managing regulatory matters and monitoring external quality performance.

Our regulatory and quality assurance departments have successfully led us through multiple quality and compliance audits by the FDA, foreign governments and customers. These departments also coordinated an audit by TÜV Rheinland of North America, leading to our European Standard, EN 13485, certification. TÜV Rheinland of North America also functions as our notified body, performing dossier reviews for some of our blood screening and

diagnostic products prior to obtaining the CE mark. In addition, our regulatory and quality assurance departments have coordinated audits by Lloyds Register Quality Assurance leading to EN ISO 13485, EN ISO 9001, EN ISO 14001 and OHSAS 18001 certifications for our wholly owned U.K. subsidiary, Molecular Light Technology Research Limited.

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Research and Development

As of December 31, 2008, we had 243 full-time and temporary employees in research and development. Our research and development expenses were $101.1 million in 2008, $97.1 million in 2007 and $84.5 million in 2006.

Employees

As of December 31, 2008, we had 991 full-time employees, of whom 208 hold advanced degrees. Of those employees, 227 were in research and development, 139 were in regulatory, clinical and quality systems, 177 were in sales and marketing, 169 were in general and administrative and 279 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. In addition, as of December 31, 2008, we had 46 temporary employees.

Geographic Information

For geographic information regarding our revenues, see Note 12 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, the timing of the execution of customer contracts, the timing of milestone payments, or the failure to achieve and receive the same, and the initiation or termination of corporate collaboration agreements. A significant portion of our costs also can 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, our new blood screening products, oncology and industrial products, as well as some of our clinical diagnostic 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. 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 have not experienced recent declines in overall blood screening or clinical diagnostics customer purchases as a result of current economic conditions, however, a continued weakening of the global and

domestic economy, or a reduction in customer spending or credit availability, could result in downward pricing pressures, delayed or decreased purchases of our 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

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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 44% of our total revenues for 2008 and 43% of total revenues for 2007. As described above, Amendment No. 11 extends to June 30, 2025 the term of our blood screening collaboration with Novartis under the 1998 Agreement. The 1998 Agreement was previously scheduled to expire by its terms in 2013. The collaboration agreement can be terminated by either party prior to the expiration of its term if the other party materially breaches the collaboration agreement and does not cure the breach following 90 days notice, or if the other party becomes insolvent or declares bankruptcy.

In July 2008, we were notified that certain blood screening assays manufactured by us for Novartis and sold outside of the United States might have been improperly stored at a Novartis third-party warehouse in Singapore. Following our established quality system, an investigation for product performance was initiated. in August 2008, we determined that, based on the results of our investigation to date, we could not fully assess the potential impact of these improper storage conditions on the ultimate performance of the product without conducting additional stability testing. As a result, we and Novartis agreed that products previously delivered to customers from this warehousing facility should be replaced and the appropriate field actions were initiated with customers and the regulatory authorities in the affected countries. While we do not expect to incur charges in connection with this event, we devoted considerable time and attention to rectifying the issues resulting from the improper storage conditions and events such as this may harm our commercial reputation.

Our agreement with Siemens, as assignee of Bayer, for the distribution of certain of our products will terminate in 2010. In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. In August 2006, we entered into a settlement agreement with Bayer regarding this arbitration and the patent litigation between the parties. Under the terms of the settlement agreement, the parties submitted a stipulated final award adopting the arbitrator s prior interim and supplemental awards, except that Bayer was no longer obligated to reimburse us $2.0 million for legal expenses previously awarded in the arbitrator s June 5, 2005 Interim Award. The arbitrator determined that the collaboration agreement should be terminated, as we requested, except as to the qualitative HCV assays and as to quantitative Analyte Specific Reagents, or ASRs, for HCV. As Bayer s assignee, Siemens retains the co-exclusive right to distribute the qualitative HCV tests and the exclusive right to distribute the quantitative HCV ASR. As a result of a termination of the collaboration agreement, we re-acquired the right to develop and market future viral assays that had been previously reserved for Siemens. The arbitrator s March 3, 2006 supplemental award determined that we are not obligated to pay an initial license fee in connection with the sale of the qualitative HIV-1 and HCV assays and that we will be required to pay running sales royalties, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents.

We rely upon bioMérieux for distribution of certain of our products in most of Europe and Australia, Rebio Gen 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 agreement with Rebio Gen terminates on December 31, 2010, although it may terminate earlier under certain circumstances. Our distribution agreement with bioMérieux terminates on May 2, 2009, although it 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.

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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 many of our products. In addition, we expect to rely on our corporate collaborators for the commercialization of those 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. While we are currently seeking other opportunities to commercialize our prototype assays in these fields, there is no guarantee we will be successful in these efforts.

The continuation of any of our collaboration agreements depends on their periodic renewal by us and our collaborators. For example, we recently entered into Amendment No. 11 with Novartis which extends to June 30, 2025 the term of our blood screening collaboration with Novartis under the 1998 Agreement. The 1998 Agreement was previously scheduled to expire by its terms in 2013. The collaboration agreement can be terminated by either party prior to the expiration of its term if the other party materially breaches the collaboration agreement and does not cure the breach following 90 days notice, or if the other party becomes insolvent or declares bankruptcy.

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 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 impact 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 with respect to 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 also may 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. For example, in July 2008 we withdrew our counterbid to acquire Innogenetics NV as a result of a higher offer made by Solvay Pharmaceuticals. Prior to withdrawing our bid, our management devoted substantial time and attention to the proposed transaction. Further, we nonetheless incurred related transaction costs, including legal, accounting and other fees.

In addition, in January 2009, we announced that we had made an approximately $132.2 million cash offer (based on the exchange rate described in the offer) for the acquisition of Tepnel Life Sciences Plc, a company registered in England and Wales, or Tepnel, pursuant to a court-sanctioned scheme of arrangement under United Kingdom law. If successful, we believe the acquisition will provide us access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in the European molecular diagnostics market. These expectations are based upon numerous assumptions that are subject to risks and

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uncertainties that could deviate materially from our estimates, and could adversely affect our operating results. Some of these risks and uncertainties include, but are not limited to, our anticipated financial performance as a result of the acquisition of Tepnel and estimated cost savings and other synergies as a result of the acquisition of Tepnel. Also, our offer to acquire Tepnel is subject to numerous conditions, including the scheme becoming effective no later than four months form the posting of the scheme document to Tepnel shareholders or such later date as we and Tepnel may agree and the court may approve. It is also possible that Tepnel could receive a competing acquisition offer and its shareholders could decline to support the transaction.

Managing the proposed acquisition of Tepnel and any other future acquisitions will entail numerous operational and financial risks, including:

- the inability to retain or replace key employees of any acquired businesses or hire enough qualified personnel to staff any new or expanded operations;
- the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;
- the exposure to federal, state, local and foreign tax liabilities in connection with any acquisition or the integration of any acquired businesses;
- the exposure to unknown liabilities;
- higher than expected acquisition and integration costs that could cause our quarterly and annual operating results to fluctuate;
- increased amortization expenses if an acquisition includes significant intangible assets;
- combining the operations and personnel of acquired businesses with our own, which could be difficult and costly;
- the risk of entering new markets; and
- integrating, or completing the development and application of, any acquired technologies and personnel with diverse business and cultural backgrounds, which could disrupt our business and divert our management s time and attention.

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

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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 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. Since August 2008, existing customers have not transitioned from the use of the Procleix HIV-1/HCV blood screening assay to the use of the Procleix Ultrio assay at the levels we anticipated. We believe this is attributable in part to the FDA s current requirements for testing blood donations, which do not currently mandate testing for HBV. Nevertheless, we believe blood collection centers will continue to focus on improving the safety of donated blood by adopting the most advanced blood screening technologies available. If 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, Becton Dickinson, Siemens and bioMérieux, currently compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. Our existing competitors or new market entrants may be in 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 impact 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. 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

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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.

Novartis, with whom we have a collaboration agreement for blood screening products, 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.

We have collaboration agreements to develop NAT products for industrial testing applications. We have limited experience operating in these markets and may not successfully develop commercially viable products.

We have collaboration agreements to develop NAT products for detecting microorganisms in selected water applications, and for microbiological and virus monitoring in the biotechnology and pharmaceutical manufacturing industries. We have limited experience applying our technologies and operating in industrial testing markets. The process of successfully developing products for application in these markets is expensive, time-consuming and unpredictable. Research and development programs to create new products require a substantial amount of our scientific, technical, financial and human resources and there is no guarantee that new products will be successfully developed. We will need to design and execute specific product development plans in conjunction with our collaborative partners and make significant investments to ensure that any products we develop perform properly, are cost-effective and adequately address customer needs.

Even if we develop products for commercial use in these markets, any products we develop may not be accepted in these markets, may be subject to competition and may be subject to other risks and uncertainties associated with these markets. For example, most pharmaceutical manufacturers rely on culture testing of their manufacturing systems, and may be unwilling to switch to molecular testing like that used in our recently launched MilliPROBE product to detect *Pseudomonas aeruginosa.* We have no experience with customer and customer support requirements, sales cycles, and other industry-specific requirements or dynamics applicable to these new markets and we and our collaborators may not be able to successfully convert customers to tests using our NAT technologies, which we expect will be more costly than existing methods. We will be reliant on our collaborators in these markets. Our interests may be different from those of our collaborators and conflicts may arise in these collaboration arrangements that have an adverse impact on our ability to develop new products. As a result of these risks and other uncertainties, we may not be able to successfully develop commercially viable products for application in industrial testing or any other new markets.

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

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

certain product lots for failure to meet product specifications. Any failure to manufacture our products in accordance with product specifications could have a material adverse effect on our revenues, profitability and commercial reputation.

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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. We believe certain of our key suppliers may be experiencing difficulties due to current economic conditions. 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. For example, there is currently a worldwide shortage of acetonitrile, which we use in the production of many of our products. We believe this shortage results from decreased worldwide production as demand falls for acetonitrile s co-product, acrylonitrile (a building block in the formulation of resins used in cars, electronic housings, and small appliances), largely attributed to the global economic slowdown. As a result, our supply of acetonitrile has been restricted along with many other companies worldwide. We are seeking to implement mitigation measures to address supply shortages, however, there can be no assurance that such measures will be successful.

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 interruption of supply. We also have single source suppliers for proposed future products. Failure to maintain existing supply relationships or to obtain suppliers for our future products, if any, 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 currently are involved in proceedings with Digene regarding our supply and purchase agreement with Roche Molecular Systems. Digene has filed a demand for binding arbitration against Roche that challenges the validity of the supply and purchase agreement. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and seeks a determination that the supply and purchase agreement is null and void. The arbitration hearing in this matter commenced October 27, 2008 and the presentation of evidence concluded November 10, 2008. In December 2008 and January 2009, the parties filed post-hearing briefs and closing arguments were presented on January 30, 2009. There can be no assurance that these matters will be resolved in our favor.

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.

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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 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 our product commercialization 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 result in delayed, or no, realization of product revenues from new products or in substantial additional costs which could decrease our profitability.

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. We expect that trial enrollment of approximately 7,000 women and trial testing will take approximately two years. However, actual trial enrollment may vary based on the prevalence of cervical disease among women in the trial or other factors. If we experience unexpected complications in conducting the trial, we may incur additional costs or experience delays or difficulties in receiving FDA approval. In addition, we cannot guarantee that the FDA will ultimately approve the use of our APTIMA HPV assay upon completion of the trial. Failure to obtain FDA approval of our APTIMA HPV assay, or delays or difficulties experienced during the clinical trial, could have a material adverse effect on our financial performance.

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

We currently offer 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 HCV testing that Siemens provides to Quest Diagnostics. The FDA restricts the sale of these products to clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform high complexity testing and also restricts the types of products that can be sold as ASRs. 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 ASR products to the FDA for clearance or approval.

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 EU foreign

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marketing authorizations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

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.

Certain of the industrial testing products that we intend to develop may be subject to government regulation, and market acceptance may be subject to the receipt of certification from independent agencies. We will be reliant on our industrial collaborators in these markets to obtain any necessary approvals. There can be no assurance that these approvals will be received.

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 Group B Streptococcus Test kits and AccuProbe *Mycobacterium tuberculosis* Culture Identification Test kits, after receiving a customer complaint indicating the customer had received a Group B Strep 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 by us, 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 collection 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 recently revised 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,

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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.

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. Revenues from our blood screening collaboration with Novartis accounted for 48% of our total revenues for 2008 and 45% of our total revenues for 2007. 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 did not receive any revenues directly from those entities. Novartis was our only customer that accounted for greater than 10% of our total revenues for 2008. Various state and city public health agencies accounted for an aggregate of 8% of our total revenues for 2008 and 9% of total revenues for 2007. 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 470 United States and foreign patents covering our products and technologies as of December 31, 2008, 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 8, 2025 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 partners 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, there may not be an adequate corrective remedy 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

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with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market and execute our business strategies.

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

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. From time-to-time in the ordinary course of business we receive communications from third parties calling our attention to patents or other intellectual property rights owned by them, with the implicit or explicit suggestion that we may need to acquire a license of such rights. We have faced in the past, and may face in the future, patent infringement lawsuits by companies that control patents for products and services similar to ours or other lawsuits alleging infringement by us of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have 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 this 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 Corporation filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution, or the IDCR, of the American Arbitration Association in New York. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and seeks a determination that our supply and purchase agreement with Roche is null and void. On July 13, 2007, the ICDR arbitrators granted our petition to join the arbitration. On August 27, 2007, Digene filed an amended arbitration demand and asserted a claim against us for tortious interference with the cross-license agreement. The arbitration hearing commenced October 27, 2008 and the presentation of evidence concluded November 10, 2008. In December 2008 and January 2009 the parties filed post-hearing briefs and closing arguments were presented on January 30, 2009. There can be no assurance that the matter will be resolved in our favor.

Pursuant to our June 1998 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 Office in the patent interference cases. From November 2007 through June 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. On May 16, 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. On June 27, 2008, the parties to the pending litigation in the United States District Court for the District of Columbia

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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 licensed from Institut Pasteur, or Novartis right to sell the HIV blood screening tests.

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, development, manufacture and marketing of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could result in the 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 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, 2008, we had approximately $230.6 million of long-lived assets, including $13.4 million of capitalized software, net of accumulated amortization, relating to our TIGRIS instrument, goodwill of $18.6 million, a $5.4 million investment in Qualigen, Inc., and $51.2 million of capitalized license and manufacturing access fees, patents, purchased intangibles and other long term assets. Additionally, we had $74.3 million of land and buildings, $16.5 million of building improvements, and $51.2 million of equipment and furniture and fixtures. 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. 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.

In June 2008, we recorded an impairment charge for the net capitalized balance of $3.5 million under our license agreement with Corixa. 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 our planned commercial approach for oncology diagnostic products, the completion of a detailed review of the intellectual property suite acquired from Corixa, including our assessment of the 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.

In the quarter ended September 30, 2008, we recorded a $1.6 million other-than-temporary loss relating to our investment in Qualigen. In making this determination, we considered a number of factors, including, among others, the share price from the company s latest financing round, the performance of the company in relation to its own operating targets and business plan, the company s revenue and cost trends, the company s liquidity and cash position, including its cash burn rate, market acceptance of the company s products and services, new products

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and/or services that the company may have forthcoming, any significant news specific to the company, the company s competitors and industry, the outlook of the overall industry in which the company operates and a third party valuation report.

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 make it difficult for us to maintain 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 profitability. Although we expect our research and development expenses as a percentage of revenue to decrease in future periods, we may not be able to generate sufficient revenues to maintain profitability in the future. Our failure to maintain profitability in the future could cause the market price of our common stock to decline.

Our short term investments 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. Risks of principal loss are 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, including as a result of current economic conditions, 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

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debt securities may impose restrictions on our operations. If we raise funds through the issuance of equity or debt convertible into equity, this issuance 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 or 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 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 segments, and we may not be able to manufacture these more complex amplified tests at costs that would allow us to maintain our historical gross margin percentages. In addition, new products that detect or quantify more than one target organism will contain significantly more complex reagents, which will increase the cost of our manufacturing processes and quality control testing. We or other parties we engage to help us may not be able to manufacture these products at a cost or in quantities that would make these products commercially viable. If we are unable to develop or contract for manufacturing capabilities on acceptable terms for our products under development, we will not be able to conduct pre-clinical, clinical and validation testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates.

Blood screening and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States and the European Union, 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 23% of our total revenues for 2008 and 20% of our total revenues for 2007. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 78% of our international revenues in 2008 and 77% in 2007. Novartis has responsibility for the international distribution of collaboration blood screening products.

We encounter risks inherent in international operations. We expect a significant portion of our sales growth, especially with respect to blood screening products, to come from expansion in international markets. If the value of

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the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. Our international sales also may be limited or disrupted by:

the imposition of government controls;

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 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.

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 reference laboratories, public health institutions and hospitals 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 Transcription-Mediated Amplification 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

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license. DiagnoCure, from whom we have an exclusive license to the PCA3 gene marker for prostate cancer, has asserted that we may have lost market exclusivity because of a failure to meet a milestone under our license and collaboration agreement. We disagree with DiagnoCure s assertion and discussions are ongoing with DiagnoCure on the issue, but we can give no assurance that this matter will be resolved in our favor.

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.

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 our two manufacturing facilities located in San Diego, California. 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 diseases, 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

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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 by-laws, 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. We will have to maintain close coordination among our various departments. 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 implemented a new 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, which could adversely affect our financial results, stock price and reputation.

Our forecasts and other forward looking statements are based upon various assumptions that are subject to significant uncertainties that may result in our failure to achieve our forecasted results.

From time to time in press releases, conference calls and otherwise, we may publish or make forecasts or other forward looking statements regarding our future results, including estimated earnings per share and other operating and financial metrics. Our forecasts are based upon various assumptions that are subject to significant uncertainties and any number of them may prove incorrect. For example, our revenue forecasts are based in large part on data and

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estimates we receive from our collaboration partners and distributors. Our achievement of any forecasts depends upon numerous factors, many of which are beyond our control. Consequently, our performance may not be consistent with management forecasts. Variations from forecasts and other forward looking statements may be material and could adversely affect our 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 invest, in all 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 214,000 square feet built-out with interior improvements in the first phase. The remaining expansion space can be used to accommodate future growth. Construction costs as of December 31, 2008 were approximately $46.3 million for this facility. These costs were capitalized as incurred and depreciation commenced upon our move-in during May 2006. Our subsidiary Molecular Light Technology Limited owns a 23,000 square-foot facility in Cardiff, United Kingdom.

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 the following facility:

Leased Facility

Location	Size	Term of Lease
Rehco Facility San Diego, California	6,438 square feet	Lease currently set to expire in August 2009 with no renewal options.

Item 3. *Legal Proceedings*

We are a party to the following litigation and are currently participating in other litigation in the ordinary course of business. 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.

Digene Corporation

In December 2006, Digene Corporation, or Digene, filed a demand for binding arbitration against F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc., collectively referred to as Roche, with the International Centre for Dispute Resolution of the American Arbitration Association in New York, or ICDR. Digene s arbitration demand challenges 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 human papillomavirus, or HPV,

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oligonucleotide products. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and seeks a determination that the supply and purchase agreement is null and void.

On July 13, 2007, the ICDR arbitrators granted our petition to join the arbitration. On August 27, 2007, Digene filed an amended arbitration demand and asserted a claim against us for tortious interference with the cross-license agreement. The arbitration hearing in this matter commenced October 27, 2008 and the presentation of evidence concluded November 10, 2008. In December 2008 and January 2009, the parties filed post-hearing briefs and closing arguments were presented on January 30, 2009.

We believe that the supply and purchase agreement is valid and that our purchases of HPV oligonucleotide products under the supply and purchase agreement are and will be in accordance with applicable law. However, there can be no assurance that the matter will be resolved in our favor.

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, 2008.

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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:

2007	High	Low
First Quarter	$ 52.86	$ 46.22
Second Quarter	$ 60.50	$ 46.61
Third Quarter	$ 67.67	$ 57.92
Fourth Quarter	$ 71.84	$ 60.81

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

As of February 13, 2009, there were 7,084 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, 2008 Repurchase Program[1]	518,100	$ 48.22	518,100	$ 215,000,000
October 1-31, 2008 Employee Transactions[2]	937	44.32		
November 1-30, 2008 Repurchase Program[1]	1,007,200	39.71	1,007,200	175,000,000
November 1-30, 2008 Employee Transactions[2]	3,655	46.89		

December 1-31, 2008 Repurchase Program[1]					175,000,000
December 1-31, 2008 Employee Transactions[2]	82		37.01		
Repurchase Program Total[1]	1,525,300		42.60	1,525,300	
Employee Transactions Total[2]	4,674	$	46.20		$

(1) In August 2008, our Board of Directors authorized the repurchase of up to $250.0 million of our common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program.

(2) During the fourth quarter of 2008, we repurchased and retired 4,674 shares of our common stock, at an average price of $46.20, withheld by us to satisfy employee tax obligations upon vesting of restricted stock granted under our 2003 Incentive Award Plan. We may make similar repurchases in the future to satisfy employee tax obligations upon vesting of restricted stock. As of December 31, 2008, we had an aggregate of 251,731 shares of restricted stock and 80,000 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, 2008 and, with respect to our consolidated balance sheets, at December 31, 2008 and 2007 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, 2005 and 2004 and the balance sheet data as of December 31, 2006, 2005, and 2004 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.

	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Statement of income data for the years ended December 31:					
Revenues:					
Product sales	$ 429,220	$ 370,877	$ 325,307	$ 271,650	$ 222,560
Collaborative research revenue	20,581	16,619	15,937	25,843	27,122
Royalty and license revenue	22,894	15,518	13,520	8,472	20,025
Total revenues	472,695	403,014	354,764	305,965	269,707
Operating expenses:					
Cost of product sales	128,029	119,641	103,882	83,900	59,908
Research and development	101,099	97,144	84,545	71,846	68,482
Marketing and sales	45,850	39,928	37,096	31,145	27,191
General and administrative	52,322	47,007	44,936	32,107	31,628
Total operating expenses	327,300	303,720	270,459	218,998	187,209
Income from operations	145,395	99,294	84,305	86,967	82,498
Net income[1]	$ 106,954	$ 86,140	$ 59,498	$ 60,089	$ 54,575
Net income per share:					
Basic	$ 1.99	$ 1.63	$ 1.15	$ 1.19	$ 1.10
Diluted	$ 1.95	$ 1.58	$ 1.12	$ 1.15	$ 1.06
Weighted average shares outstanding:					
Basic	53,708	52,975	51,538	50,617	49,429
Diluted	54,796	54,522	53,101	52,445	51,403
Balance sheet data as of December 31:					
Cash, cash equivalents and short-term investments	$ 505,178	$ 433,494	$ 289,913	$ 220,288	$ 193,826
Working capital	580,237	518,408	342,062	262,375	234,202
Total assets	869,531	789,053	623,839	510,236	411,082
Stockholders equity[2][3]	813,760	738,040	570,208	447,373	361,029

(1) We adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payment, on January 1, 2006. For 2005 and 2004, net income including pro forma stock-based compensation expense was $45.3 million ($0.86 per diluted share) and $41.9 million ($0.82 per diluted share), respectively.

(2) Effective January 1, 2006, we adopted Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements, which resulted in an increase to beginning retained earnings of $3.9 million.

(3) Effective January 1, 2007, we adopted Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes, which resulted in a reduction in beginning retained earnings of approximately $1.0 million.

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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a safe harbor for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, p intends, estimates, could, should, would, continue, seeks, or anticipates, or other similar words, includi the negative. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. These risks and uncertainties include those under the caption Item 1A Risk Factors. We assume no obligation to update any forward-looking statements. The audited consolidated financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto for the years ended December 31, 2008, 2007 and 2006, included elsewhere in this Annual Report on Form 10-K.

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for screening donated human blood. We also develop and manufacture nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. We have 26 years of research and development experience in nucleic acid detection, and our products, which are based on our patented nucleic acid testing, or NAT, technology, are used daily in clinical laboratories and blood collection centers throughout the world.

We have achieved strong growth since 2002 in both revenues and earnings, primarily due to the success of our clinical diagnostic products for sexually transmitted diseases, or STDs, and blood screening products that are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, hepatitis C virus, or HCV, hepatitis B virus, or HBV, and West Nile Virus, or WNV. Under our collaboration agreement with Novartis Vaccines and Diagnostics, Inc., or Novartis, formerly known as Chiron Corporation, or Chiron, we manufacture blood screening products, while Novartis is responsible for marketing, sales and service of those products, which Novartis sells under its trademarks.

Recent Events

Financial Results

Product sales for 2008 were $429.2 million, compared to $370.9 million in 2007, an increase of 16%. Total revenues for 2008 were $472.7 million, compared to $403.0 million in 2007, an increase of 17%. Net income for 2008 was $107.0 million ($1.95 per diluted share), compared to $86.1 million ($1.58 per diluted share) in 2007, an increase of 24%.

Offer to Acquire Tepnel Life Sciences

In January 2009, we made a recommended cash offer to acquire Tepnel Life Sciences Plc, or Tepnel, a company registered in England and Wales, for approximately $132.2 million (based on the exchange rate described in the offer). Our offer is subject to certain conditions, including approval of the offer by a majority in number representing 75% or more in value of Tepnel s shareholders entitled to vote with respect to the proposed transaction. If we are successful in our acquisition of Tepnel, we believe the acquisition will provide us access to growth opportunities in transplant

diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in the European molecular diagnostics market.

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Stock Repurchase Program

In August 2008, our Board of Directors authorized the repurchase of up to $250.0 million of our common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During 2008, we repurchased and retired approximately 1,705,400 shares under this program at an average price of $43.96, or approximately $75.0 million in total.

Voluntary Counterbid to Acquire Innogenetics

In June 2008, following a bid by Solvay Pharmaceuticals, we launched a conditional counterbid to acquire 100% of the outstanding shares, warrants and convertible bonds of Innogenetics NV, a Belgian molecular diagnostics company, for approximately 215 million. On July 9, 2008, Solvay Pharmaceuticals submitted a higher bid to acquire Innogenetics and we formally withdrew our counterbid. Included in our general and administrative expenses for 2008 are approximately $2.0 million of costs associated with our counterbid to acquire Innogenetics.

Corporate Collaborations

Novartis

In January 2009, we entered into an agreement, referred to herein as Amendment No. 11, with Novartis to amend the June 11, 1998 collaboration agreement, or the 1998 Agreement, between the parties. The effective date of Amendment No. 11 is January 1, 2009. Amendment No. 11 extends to June 30, 2025 the term of our blood screening collaboration with Novartis under the 1998 Agreement. The 1998 Agreement was scheduled to expire by its terms in 2013.

The 1998 Agreement provided that we were solely responsible for manufacturing costs incurred in connection with the collaboration, while Novartis was responsible for sales and marketing expenses associated with the collaboration. Amendment No. 11 provides that, effective January 1, 2009, we will recover 50% of our costs of goods sold incurred in connection with the collaboration. In addition, we will receive a percentage of the blood screening assay revenue generated under the collaboration, as described in the next paragraph.

The 1998 Agreement provided that we share revenue from the sale of blood screening assays under the collaboration with Novartis. Under the terms of the 1998 Agreement, as previously amended, our share of revenue from any assay that included a test for HCV was 45.75%. Amendment No. 11 modifies our share of such revenues, initially reducing it to 44% in 2009. Our share of blood screening assay revenue increases in subsequent years as follows: 2010-2011, 46%; 2012-2013, 47%; 2014, 48%; and 2015, 50%. Our share of blood screening assay revenue is fixed at 50% from January 1, 2015 though the remainder of the amended term of the agreement. Under Amendment No. 11, our share of blood screening assay revenue from any assay that does not test for HCV remains at 50%. As discussed above, we are entitled to our designated percentage of revenue from the sale of blood screening assays as well as the recovery of 50% of our costs of goods sold. Amendment No. 11 also provides that Novartis will reduce the amount of time between product sales and payment of our share of blood screening assay revenue from 45 days to 30 days.

As part of Amendment No. 11, the parties have agreed, and Novartis has agreed to provide certain funding, to customize our Panther instrument, a fully automated molecular testing platform now in development, for use in the blood screening market. Novartis has also agreed to pay us a milestone payment upon the first commercial sale of the Panther instrument. The parties will equally share 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 us with certain funding in support of initial research and development.

3M Corporation

In June 2008, 3M Corporation, or 3M, discontinued our collaboration to develop rapid, molecular tests for healthcare-associated infections, or HCAIs, due to technical incompatibilities between our NAT technologies and

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3M s proprietary microfluidics instrument platform. Under the terms of the discontinued agreement, we were responsible for assay development, which 3M funded. 3M had also agreed to pay us milestones based on technical and commercial progress. We earned the first of these milestones, related to assay feasibility, in the fourth quarter of 2007. Based on the termination of the agreement, in June 2008 we recorded $2.7 million in collaborative research revenue that was previously deferred. In December 2008, we received an additional $0.4 million from 3M for costs incurred to wind down the collaboration. We are currently exploring other opportunities to commercialize our prototype assays in the HCAI field.

Millipore Corporation

In January 2008, Millipore Corporation commenced commercialization of the first MilliPROBE assay, developed under our industrial testing collaboration, which targets the bacterium *Pseudomonas aeruginosa* and is designed as an in-process, early warning system to provide faster, more effective detection of *Pseudomonas aeruginosa* in purified water used during drug production. The assay was designed to ensure a higher degree of water quality throughout manufacturing processes where the contaminant can be a serious quality and safety concern. We believe faster detection will enable biopharmaceutical manufacturers to reduce downstream processing risks, optimize product yields and improve final product quality.

Product Development

In August 2008, the Food and Drug Administration, or FDA, approved the Procleix Ultrio assay to screen donated blood, plasma, organs and tissues for HBV in individual blood donations or in pools of up to 16 blood samples on the enhanced semi-automated system, or eSAS, and on the fully automated, high-throughput TIGRIS system. The FDA had previously approved the assay to screen donated blood for HIV-1 and HCV.

In May 2008, we launched our APTIMA HPV assay in Europe. The APTIMA HPV assay has been CE-marked for use on the fully automated, high-throughput TIGRIS system and our semi-automated Direct Tube Sampling, or DTS, system.

In March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. The investigational APTIMA HPV assay is an amplified nucleic acid test that is designed to detect 14 types of high-risk human papillomavirus, or HPV, that are associated with cervical cancer. More specifically, the assay is designed to detect two 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 acids, or DNA. We expect to enroll approximately 7,000 women in the trial. Actual enrollment, however, may vary based on the prevalence of cervical disease among women in the trial. The trial enrollment and testing are expected to take approximately two years. The APTIMA HPV assay is designed to run on our fully automated, high-throughput TIGRIS instrument system and on our future medium-throughput instrument platforms.

Final Payment Received in Litigation Settlement

In June 2006, we entered into a Short Form Settlement Agreement with Bayer HealthCare LLC and Bayer Corp., collectively Bayer, to resolve patent litigation we filed against Bayer in the United States District Court for the Southern District of California and to resolve separate commercial arbitration proceedings between the parties. On August 1, 2006, the parties signed final, definitive settlement documentation, referred to herein as the Settlement Agreement. All litigation and arbitration proceedings between us and Bayer were terminated pursuant to the Settlement Agreement.

Pursuant to the terms of the Settlement Agreement, Bayer paid us an initial license fee of $5.0 million in August 2006. Siemens, as assignee of Bayer, paid us $10.3 million as a one-time royalty on January 31, 2007 and $16.4 million as a one-time royalty on January 31, 2008. As a result of these royalty payments, Siemens rights to the patents subject to the Settlement Agreement are fully paid-up and royalty free.

Pursuant to the Settlement Agreement, we obtained certain contract and patent rights to distribute qualitative HIV-1 and HCV tests through October 2010. We also obtained an option to extend our rights through the life of

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certain HIV-1 and HCV patents. The option also permits us to elect to extend our rights to future instrument systems (but not to the TIGRIS instrument). We are required to exercise the option prior to the expiration of the existing rights in October 2010 and, if exercised, pay a $1.0 million fee.

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

Product sales also include the sales or rental revenue associated with the delivery of our proprietary integrated instrument platforms that perform our diagnostic assays. Generally, we provide our instrumentation to clinical laboratories 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 amounts 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 their 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 our 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.

Shipments of our blood screening products in the United States and other countries in which the products have not received regulatory approval are recorded 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 commercial approval, we classify sales of these products as product sales in our consolidated financial statements.

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We follow the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, for multiple element revenue arrangements. EITF Issue No. 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the deliverables in a revenue arrangement constitute separate units of accounting according to the EITF Issue No. 00-21 separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue-recognition policy must be determined for the entire arrangement, and all non-refundable upfront license fees are deferred and recognized as revenues on a straight-line basis over the expected term of our continued involvement in the collaborations.

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 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 sheet.

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. Non-refundable license fees are recognized over the related performance period or at the time we have satisfied all performance obligations.

Valuation of inventories

We record valuation adjustments to our inventories balances for estimated excess and obsolete inventories equal to the difference between the cost of such inventories 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 in the marketplace if certain compliance requirements are not met. We have made assumptions that are reflected in arriving at our net inventories value based on information currently available to us. If future product demand, regulatory constraints or other market conditions are less favorable than those projected by management, additional inventories 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 inventories 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 inventories reserves that are directly applicable to such products.

For 2008, 2007 and 2006, total gross charges to our inventories reserves have not impacted gross margin, as a percentage of sales, by more than 1.8%. We believe that similar charges to estimated inventories reserves, and the related effect on gross margins, are reasonably likely in the future. Historically, changes to inventories valuation reserves in subsequent periods have not materially affected cost of product sales.

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Valuation of goodwill and long-lived assets

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, generally in the fourth quarter of each year.

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, an impairment loss is recognized if the carrying amount exceeds its fair value.

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 in accordance with Statement of Financial Accounting Standards, or SFAS, No. 86, Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed. 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, 2008, capitalized software development costs related to products for use on our TIGRIS instrument totaled $13.4 million, net of accumulated amortization. We began amortizing the capitalized software costs on a straight-line basis over 120 months in May 2004, coinciding with the general release of TIGRIS instruments to our customers.

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.

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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 subject to the provisions of revised SFAS No. 123(R), Share-Based Payment. Under SFAS No. 123(R), 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. We have no awards with market or performance conditions. We adopted the provisions of SFAS No. 123(R) on January 1, 2006, using a modified prospective application. 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 values 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 in accordance with SFAS No. 123(R) and the Securities and Exchange Commission s Staff Accounting Bulletin No. 107, or SAB No. 107, 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, 2008, we used a weighted average stock price volatility of 34%. If our stock price volatility assumptions were to increase 25% to 42%, the weighted average estimated fair value of stock options granted during the year ended December 31, 2008 would increase by $3.45 per share, or 19%.

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, 2008 we used an expected term of 4.2 years. If our expected term were to increase by one year to 5.2 years, the weighted average estimated fair value of stock options granted during the year ended December 31, 2008 would increase by $2.29 per share, or 12%.

SFAS No. 123(R) requires forfeitures 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 when deemed necessary.

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Adoption of recent accounting pronouncements

SFAS No. 157

Effective January 1, 2008, we adopted SFAS No. 157, Fair Value Measurements, for financial assets and liabilities measured at fair value. SFAS No. 157 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.

Following is a description of our valuation methodologies used for instruments measured at fair value. Where appropriate, the description includes details of the valuation models, the key inputs to those models, as well as any significant assumptions.

Available-for-sale securities

Our available-for-sale securities are comprised of tax advantaged municipal securities 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, 2008, we reported $15.5 million and $449.7 million of assets measured at fair value on a recurring basis as Level 1 and 2, respectively.

Equity investment in private company

In 2006, we invested in Qualigen, Inc., or Qualigen, a private company. 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 valued initially based upon the transaction price under the cost method of accounting. 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). At December 31, 2008, we reported $5.4 million, or 1.1%, of assets measured at fair value on a non-recurring basis as Level 3 in the fair value hierarchy.

We record impairment charges when we believe an investment has experienced a decline that is 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

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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 impact on our results of operations.

During the third quarter of 2008, we received financial statements from Qualigen that indicated potential issues towards the execution of their long-term sales plans. As a result, with the consultation and assistance of a third party valuation company, and the support of Qualigen management, we performed a valuation of Qualigen. The valuation of our 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 our investment between $4.2 million and $6.6 million. We concluded that an equal weighting of the market and income methods was appropriate and as a result of this valuation our ownership of Qualigen was valued at approximately $5.4 million. We believe that the decline in the value of this investment from our initial cost basis was an other-than-temporary impairment of our investment and thus we recorded an impairment charge of $1.6 million to write down the carrying value of our equity interest. This amount is included in Other income/(expense) on the consolidated statements of income.

SFAS No. 159

Effective January 1, 2008, we adopted SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115, which expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred (e.g., debt issue costs). The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. During 2008, we did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

EITF Issue No. 07-3

Effective January 1, 2008, we adopted EITF Issue No. 07-3, Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities. EITF Issue No. 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. There was no material financial statement impact as a result of adoption.

Pending adoption of recent accounting pronouncements

SFAS No. 141(R)

In December 2007, the Financial Accounting Standards Board, or FASB, issued SFAS No. 141(R), Business Combinations. SFAS No. 141(R) changes the requirements for an acquirer s recognition and measurement of the assets acquired and liabilities assumed in a business combination, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, in-process research and development and restructuring costs. In

addition, under SFAS No. 141(R), changes in an acquired entity s deferred tax assets and uncertain tax positions after the measurement period will impact income tax expense. This statement is effective with respect to business combination transactions for which the acquisition date is after December 31, 2008.

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SFAS No. 160

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin, or ARB, No. 51). SFAS No. 160 requires that noncontrolling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the non-controlling interest be separately identified in the income statement, that changes in a parent s ownership interest while the parent retains its controlling interest be accounted for as equity transactions, and that any retained noncontrolling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value. This statement is effective for fiscal years beginning after December 31, 2008, and shall be applied prospectively. However, the presentation and disclosure requirements of SFAS No. 160 are required to be applied retrospectively for all periods presented. The retrospective presentation and disclosure requirements of this statement will be applied to any prior periods presented in financial statements for the fiscal year ending December 31, 2009, and later periods during which we have a consolidated subsidiary with a noncontrolling interest. As of December 31, 2008, we do not have any consolidated subsidiaries in which there is a noncontrolling interest.

EITF Issue No. 07-1

In November 2007, the FASB ratified EITF Issue No. 07-1, Accounting for Collaborative Agreements Related to the Development and Commercialization of Intellectual Property. EITF Issue No. 07-1 defines collaborative agreements as a contractual arrangement in which the parties are active participants to the arrangement and are exposed to the significant risks and rewards that are dependent on the ultimate commercial success of the endeavor. Additionally, it requires that revenue generated and costs incurred on sales to third parties as it relates to a collaborative agreement be recognized as gross or net based on EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent. Essentially, this requires the party that is identified as the principal participant in a transaction to record the transaction on a gross basis in its financial statements. It also requires payments between participants to be accounted for in accordance with already existing generally accepted accounting principles, unless none exist, in which case a reasonable, rational, consistent method should be used. We will adopt this guidance effective January 1, 2009 for all collaboration agreements existing as of that date. We do not believe that the adoption of EITF Issue No. 07-1 will have a material impact on our financial statements, as we believe all collaboration agreements are currently in compliance with this standard.

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)	2008	2007	2006	2008/2007	2007/2006
Product Sales	$ 429.2	$ 370.9	$ 325.3	16%	14%
As a percent of total revenues	91%	92%	92%		

Our primary source of revenue comes from product sales, which consist primarily of the sale of clinical diagnostic and blood screening products in the United States. Our clinical diagnostic products include our APTIMA, PACE, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. The principal customers for our

clinical diagnostics products include large reference laboratories, public health institutions and hospitals. The blood screening assays and instruments we manufacture are marketed 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

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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 16% in 2008 from 2007. The $58.3 million increase was primarily attributed to $31.9 million in higher blood screening assay sales and $29.6 million in higher APTIMA assay sales, partially offset by a $6.6 million decrease in PACE product sales as customers continue to convert to the more sensitive amplified APTIMA product line.

Diagnostic product sales, including assay, instrument, and ancillary 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 assay and the availability of our fully automated TIGRIS instrument. Overall APTIMA growth was partially offset by a $6.6 million decrease in PACE product sales as customers continue to convert to the more sensitive amplified APTIMA product line. In 2008, APTIMA sales were approximately 87% of our STD product sales versus PACE sales of 13%. In 2007, APTIMA represented 82% of STD product sales, and PACE 18%. Average pricing in 2008 related to our APTIMA products decreased approximately 3% from 2007 primarily related to strong unit growth in our corporate account sector. Approximately $20.3 million of our diagnostic product sales are denominated in currencies other than the U.S. dollar. In 2008, we estimate that the growth of our 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 related sales, including assay, instrument, and ancillary 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, United States 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 an adjustment to service costs previously deducted by Novartis prior to arriving at our net share of revenue under the collaboration. In addition, we estimate that $5.0 million of the growth in 2008 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.

Product sales increased 14% in 2007 from 2006. The $45.6 million increase was primarily attributed to $32.3 million in higher APTIMA assay sales and $21.8 million in higher blood screening assay sales, partially offset by a $10.6 million decrease in PACE product sales.

Diagnostic product sales, including assay, instrument, and ancillary sales, represented $199.2 million, or 54% of product sales in 2007, compared to $171.2 million, or 53% of product sales in 2006. This $28.0 million increase was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions, and market share gains attributed to the assays clinical performance and the availability of our fully automated TIGRIS instrument. The remaining growth in diagnostics was primarily the result of an increase in diagnostic instrumentation sales, which increased by $5.9 million from 2006 levels. Overall APTIMA growth was partially offset by a related $10.6 million decrease in PACE product sales as customers converted to the more sensitive amplified APTIMA product line. 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. In 2007, APTIMA sales were approximately 82% of our STD product sales versus PACE sales of 18%. In

2006, APTIMA represented 72% of STD product sales, and PACE 28%. Average pricing in 2007 related to our primary APTIMA products remained consistent with 2006 levels.

In 2006, our WNV assay was approved on our semi-automated instrument system. As a result, revenues from the sale of our WNV assay began to be recorded as product sales at higher commercial prices. Prior to approval,

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revenues were recorded as collaborative research revenues, which were solely based upon cost recovery pricing. In 2006, we recorded approximately $9.2 million of WNV sales as collaborative research revenue. In 2007, the increase in WNV product sales was $14.8 million over 2006 levels as a result of a full year of recognizing revenue as product sales and higher pricing associated with post-approval commercial pricing. In addition, in 2007, aggregate product sales related to sales of our Procleix HIV-1/HCV assay and our Ultrio assay, which includes an assay for HBV that is combined in one test with the HIV-1/HCV assay, increased by $7.0 million over 2006 levels, primarily attributable to an increase in international testing volumes and higher world wide shipment volumes.

Blood screening related sales, including assay, instrument, and ancillary sales, represented $171.7 million, or 46% of product sales in 2007, compared to $154.1 million, or 47% of product sales in 2006. The $17.6 million increase in blood screening sales during 2007 was principally attributed to the approval and commercial launch of our WNV assay for use on the TIGRIS instrument, as well as international expansion of Procleix Ultrio sales. Our share of blood screening revenues is based upon sales of assays by Novartis, on blood donation levels and the related price per donation. In 2007, United States blood donation volumes screened using the Procleix HIV-1/HCV assay were relatively consistent with 2006 levels, as was the related pricing. International revenues increased as blood donations screened using either the Procleix HIV-1/HCV assay or the Procleix Ultrio assay grew approximately 7% from 2006 levels, as the Procleix Ultrio product further penetrated international markets. Partially offsetting the growth of WNV and the Procleix and Ultrio products in 2007 was a reduction in the sales of blood screening instrumentation, which declined by $4.2 million from 2006 levels. The decline in the sale of blood screening instrumentation was primarily driven by a decrease in the sales of spare parts and components for the TIGRIS system, as Novartis began to acquire these parts and components directly from the manufacturer of the TIGRIS instrument in early 2007.

	Years Ended December 31,			% Change	
(Dollars in millions)	2008	2007	2006	2008/2007	2007/2006
Collaborative Research Revenue	$ 20.6	$ 16.6	$ 16.0	24%	4%
As a percent of total revenues	4%	4%	4%		

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 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. 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 increased 24% in 2008 from 2007. The $4.0 million increase was primarily due to the $10.0 million milestone payment 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 nears completion, and a $3.9 million decrease in funding from 3M related to our food testing program that was discontinued in November 2007.

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Collaborative research revenue increased 4% in 2007 from 2006. The $0.6 million increase from the prior year was primarily the result of a $4.1 million increase in reimbursement from Novartis for blood screening development programs, a $3.9 million increase from 3M for work on the food testing and healthcare-associated infection programs, and a $3.6 million increase from the United States Army Medical Research and Material Command for work on the development of improved cancer diagnostic assays. These increases were partially offset by a $9.2 million decrease in revenue from Novartis related to deliveries of WNV tests on a cost recovery basis until May 2006 (now recorded as product sales) and a $1.4 million decrease in reimbursement from one of our industrial partners for certain assay development costs.

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 revenues, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate additional collaborative research revenues 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. These relationships may not be established or maintained and current collaborative research revenue may decline.

	Years Ended December 31,			% Change	
(Dollars in millions)	2008	2007	2006	2008/2007	2007/2006
Royalty and License Revenue	$ 22.9	$ 15.5	$ 13.5	48%	15%
As a percent of total revenues	5%	4%	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.

Our royalty and license revenue during 2008 and 2007 consisted primarily of settlement payments received from Siemens, as an assignee of Bayer ($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 royalty and license revenue during 2008 from 2007 was primarily the result of $6.1 million in higher amounts received from Bayer 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 increased 15% in 2007 from 2006. The $2.0 million increase in royalty and license revenue in 2007 was principally attributed to a $5.3 million increase in license fee revenue from Bayer pursuant to the terms of our settlement agreement, partially offset by a decrease of $3.3 million, the amount received from bioMérieux in 2006 for out-licensing of RNA technology for which options on additional targets were not exercised in 2007.

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

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market and capitalize on our technologies. We may not be able to do so and future royalty and license revenue may decline.

(Dollars in millions)	Years Ended December 31, 2008	2007	2006	% Change 2008/2007	2007/2006
Cost of Product Sales	$ 128.0	$ 119.6	$ 103.9	7%	15%
Gross profit margin as a percent of product sales	70%	68%	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.

In addition, we manufacture significant quantities of materials, development lots, and clinical trial lots of product prior to receiving FDA approval 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 outside the United States is capitalized to inventory and classified as cost of product sales upon shipment.

Our blood screening manufacturing facility has operated, and will continue to operate, below its potential capacity for the foreseeable future. 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 Investigational New Drug, or IND, application, are classified as R&D expense prior to FDA approval.

Cost of 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 versus 2007 as a result of higher production volumes.

Cost of product sales increased 15% in 2007 from 2006. The $15.7 million increase in cost of product sales was primarily due to $5.9 million in higher Procleix Ultrio assay shipments, $5.1 million in higher APTIMA shipments, $2.0 million in higher WNV assay shipments, and $1.7 million in higher instrument amortization costs associated with a higher installed base of instruments.

Our gross profit margin as a percentage of product sales increased to 70% in 2008 from 68% in 2007 and 2006. 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, partially offset by increased instrument sales, which have lower margins, and instrument related costs and increased amortization of capitalized intangible assets.

Cost of product 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 are 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 from sales of TIGRIS instruments to Novartis, which totaled $12.4 million, $9.4 million, and $9.7 million during 2008, 2007 and 2006, respectively. Under our collaboration agreement with Novartis, we sell TIGRIS instruments to them at prices that approximate cost. 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.

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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. The greater number of tests required for smaller pool sizes will increase our variable manufacturing costs, including costs of raw materials and labor. In 2008, we were responsible for 100% of the cost of goods sold pursuant to our collaboration agreement with Novartis. Effective January 1, 2009, our amended collaboration agreement with Novartis provides that we will recover 50% of our costs of goods sold incurred in connection with the collaboration. 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 will charge to the end user or the degree to which smaller pool size testing will be adopted across the markets in which we sell our products.

	Years Ended December 31,			% Change	
(Dollars in millions)	2008	2007	2006	2008/2007	2007/2006
Research and Development	$ 101.1	$ 97.2	$ 84.6	4%	15%
As a percent of total revenues	21%	24%	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 the development and validation activities for our PCA3 and HPV assays, development of Panther, our fully automated system for low and mid-volume laboratories, assay integration activities for Panther, development and validation of assays for blood screening and industrial applications, and on-going research and early stage development activities. Although total R&D dollars may increase over time, we expect our R&D expenses as a percentage of total revenues to decline in future years.

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 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 a $0.8 million decrease in professional fees for consultant services no longer utilized in 2008.

R&D expenses increased 15% in 2007 from 2006. The $12.6 million increase in R&D spending was primarily due to $4.1 million in oligonucleotide purchases for development lot builds, $2.9 million in higher allocations of facilities and information systems, $2.4 million in higher outside services to support development projects such as industrial applications, a $1.6 million increase in salaries and personnel-related expenses due to higher staffing levels, a $1.4 million increase in depreciation and amortization due to replacement of equipment in 2007 and a $1.3 million increase in professional fees. These increases were partially offset by a $3.0 million decrease in stock-based compensation expense due to increased forfeitures related to employee turnover.

(Dollars in millions)	Years Ended December 31, 2008	2007	2006	% Change 2008/2007	2007/2006
Marketing and Sales	$ 45.9	$ 39.9	$ 37.1	15%	8%
As a percent of total revenues	10%	10%	10%		

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

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.

Marketing and sales expenses increased 8% in 2007 from 2006. The $2.8 million increase in marketing and sales expenses was primarily due to a $1.6 million increase in spending for marketing research and materials related to international expansion and $1.2 million in higher salaries and personnel-related expenses to support product sales growth, partially offset by a $0.5 million decrease in stock-based compensation expense due to increased forfeitures related to employee turnover.

	Years Ended December 31,			% Change	
(Dollars in millions)	2008	2007	2006	2008/2007	2007/2006
General and Administrative	$ 52.3	$ 47.0	$ 44.9	11%	5%
As a percent of total revenues	11%	12%	13%		

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 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. These increases were partially offset by a $1.2 million decrease in relocation expenses associated with senior level personnel hired in the prior year.

G&A expenses increased 5% in 2007 from 2006. The $2.1 million increase in G&A expenses was primarily the result of a $5.3 million increase in salaries and personnel-related expenses due principally to increased personnel and a $0.7 million increase in service contracts due principally to software and equipment upgrades. These increases were offset by a $2.4 million decrease in legal fees, as 2006 included fees associated with our two patent infringement lawsuits against Bayer, including a $2.0 million payment to our outside litigation counsel in connection with the Bayer settlement, as well as a $1.3 million decrease in stock-based compensation expense due to increased forfeitures related to employee turnover.

	Years Ended December 31,			% Change	
(Dollars in millions)	2008	2007	2006	2008/2007	2007/2006
Interest income	$ 16.8	$ 12.8	$ 8.3	31%	54%
Interest expense			(0.1)	N/M	N/M
Other income / (expense)	(1.3)	(0.5)	0.5	160%	N/M

Total other income, net	$ 15.5	$ 12.3	$ 8.7	26%	41%

The $4.0 million increase in interest income in 2008 from 2007 was primarily a result of higher average balances of our short-term investments, 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 from realized foreign currency exchange losses.

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The $3.6 million net increase total other income, net in 2007 from 2006 was primarily due to an increase of $4.5 million in interest income resulting from higher average balances of our short-term investments, offset by $0.9 million in realized foreign currency exchange losses.

	Years Ended December 31,			% Change	
(Dollars in millions)	2008	2007	2006	2008/2007	2007/2006
Income Tax Expense	$ 53.9	$ 25.5	$ 33.5	111%	(24)%
As a percentage of income before tax	34%	23%	36%		

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.

Income tax expense decreased 24% in 2007 from 2006 and our effective tax rate decreased to 23% of 2007 pretax income, compared to 36% of 2006 pretax income. The decrease was principally attributed to the 2007 completion of federal and state audits noted above, and higher tax-exempt interest.

Liquidity and capital resources

	2008	2007	2006	Amount Change From 2007 to 2008
		(In thousands)		
As of December 31:				
Cash, cash equivalents and short-term investments	$ 505,178	$ 433,494	$ 289,913	$ 71,684
Working capital	580,237	518,408	342,062	61,829
Current ratio	13:1	14:1	8:1	

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 short-term investments include tax advantaged municipal securities with a minimum Moody s credit rating of A3 and a minimum Standard & Poor s credit rating of A-. As of December 31, 2008, we did not hold auction rate 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, 2008, our portfolios had an average term of three years and an average credit quality of AA3 as defined by Moody s.

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Our working capital at December 31, 2008 increased $61.8 million from December 31, 2007, primarily due to increased cash balances generated from operations. Days sales outstanding, or DSO, for the year ended December 31, 2008 was flat compared to the prior year at 28 days. Days sales in inventory decreased slightly to 147 days at December 31, 2008 from 153 days at December 31, 2007 due to increased sales volume and cost of product sales.

	2008	2007	2006	Amount Change From 2007 to 2008
		(In thousands)		
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	$ 178,253	$ 109,584	$ 101,020	$ 68,669
Investing activities	(139,888)	(183,424)	(79,208)	43,536
Financing activities	(53,534)	61,812	33,153	(115,346)
Purchases of property, plant and equipment (included in investing activities above)	(39,348)	(23,096)	(50,760)	(16,252)

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. 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 to continue the repurchase of our common stock under our stock repurchase program, as well as for strategic purchases which may include businesses and/or technologies complimentary to our business. Certain R&D costs may be funded under collaboration agreements with partners.

The $68.7 million increase in net cash provided by operating activities during 2008 compared to 2007 was primarily due to $20.8 million in higher net income, a $23.6 million decrease in accounts receivable due to collections from our customers and decreases in collaborative partner funding, a $12.1 million reduction in tax benefits from stock-based compensation, a $9.0 million increase in inventories, an $8.5 million decrease in prepaid expenses related to higher upfront fees paid in 2007 for the purchase of TIGRIS instruments, a $6.7 million reduction of deferred revenue related to the termination of our collaboration agreement with 3M, a $6.2 million increase in accounts payable balances related to increased cost of sales and timing of payments, a $4.8 million increase in deferred tax assets for impairments not yet tax deductible and the excess of current year stock-based compensation expense over the related tax deductions, a $3.5 million impairment charge associated with our Corixa license agreement and a $2.3 million increase in amortization of premiums on investments.

The $43.5 million decrease in net cash used in investing activities during 2008 compared to 2007 was principally attributed to a $16.3 million increase in capital expenditures and a payment of $10.0 million to Roche associated with commercialization of our CE-marked HPV product. These increases were offset by a $65.1 million net decrease in purchases (net of sales) of short-term investments. Capital spending increased from 2007 levels due primarily to the purchase of our blood screening facility, which closed in the first quarter of 2008.

The $115.3 million decrease in net cash provided by financing activities during 2008 compared to 2007 was principally attributed to $75.0 million used in 2008 to repurchase and retire 1,705,400 shares of our common stock under our stock repurchase program and a $28.4 million decrease in proceeds from the exercise of stock options and the associated $12.1 million decrease in excess tax benefits. We receive cash from the exercise of employee stock

options and proceeds from the sale of common stock pursuant to the ESPP. We expect fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock, along with other factors.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2009, under which we may borrow up to $10.0 million, subject to a borrowing base formula, at the bank s prime rate, or

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at LIBOR plus 1.0%. At December 31, 2008, we did not have any amounts outstanding under the bank line and we have not taken advances against the line since inception.

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

We may from time to time consider the acquisition of businesses and/or technologies complementary to our business. We could require additional equity or debt financing if we were to engage in a material acquisition in the future. For example, in January 2009, we made a recommended cash offer to acquire Tepnel for approximately $132.2 million (based on the exchange rate described in the offer). Our offer is subject to certain conditions, including approval of the offer by a majority in number representing 75% or more in value of Tepnel s shareholders entitled to vote with respect to the proposed transaction. If we are successful in our acquisition of Tepnel, we believe the acquisition will provide us access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in the European molecular diagnostics market.

Contractual obligations and commercial commitments

Our contractual obligations due for purchase commitments, collaborative agreements and minimum royalties as of December 31, 2008 were as follows (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Material purchase commitments[1]	$ 24,822	$ 24,822	$	$	$
Collaborative commitments[2]	5,005	1,416	1,961	250	1,378
Minimum royalty commitments[3]	1,400	175	525	350	350
Total[4]	$ 31,227	$ 26,413	$ 2,486	$ 600	$ 1,728

(1) Amounts represent our minimum purchase commitments from key vendors for the TIGRIS and Panther instruments, as well as raw materials used in manufacturing. Of the $24.8 million total, $15.9 million is expected to be used to purchase TIGRIS instruments, of which we anticipate that approximately $7.0 million of instruments will be sold to Novartis. Not included in the $24.8 million is $9.6 million expected to be used to purchase validation, pre-production and production instruments, and associated tooling, pursuant to our development agreement with Stratec for the Panther instrument and potential minimum purchase commitments under our supply agreement. Our obligations under the supply agreement are contingent on successful completion of all activities under the development agreement.

(2) In addition to the minimum payments due under our collaborative agreements, we may be required to pay up to $12.2 million in milestone payments, plus royalties on net sales of any products using specified technology. We

may also be required to pay up to $6.1 million in future development costs in the form of milestone payments.

(3) Amounts represent our minimum royalties due on the net sales of products incorporating licensed technology and subject to a minimum annual royalty payment. During 2008, we recorded $5.2 million in royalty costs related to our various license agreements.

(4) 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 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.

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Liabilities associated with uncertain tax positions, currently estimated at $6.2 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.

Additionally, we have liabilities for deferred employee compensation which totaled $3.7 million at December 31, 2008. The payments related to the deferred compensation are not included in the table above because they are typically dependent upon when certain key employees retire or otherwise leave the Company. At this time, we cannot reasonably predict when these events may occur. Liabilities for deferred employee compensation are offset by deferred compensation assets, which totaled $3.5 million at December 31, 2008.

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***

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. 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 short-term investment grade securities. A 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately $9.0 million. While changes in our interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our statement of income until the investment is sold or if a reduction in fair value is determined to be a permanent impairment.

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. The functional currency of our wholly owned subsidiaries Gen-Probe UK Limited and Molecular Light Technology Limited and its subsidiaries is the British pound. The functional currency of Gen-Probe Italia S.r.l. and Gen-Probe Deutschland GmbH is the Euro. Accordingly, the balance sheet accounts of these subsidiaries are translated into United States dollars using the exchange rate in effect at the balance sheet date and revenue and expenses are translated using the average exchange rates in effect during the period. The gains and losses from foreign currency translation of the financial statements of these subsidiaries are recorded directly as a separate component of stockholders equity under the caption Accumulated other comprehensive income.

Our total payables denominated in foreign currencies as of December 31, 2008 were not material. Our receivables by foreign currency as of December 31, 2008 reflected in U.S. dollar equivalents were as follows (in thousands):

Swiss Franc	$ 16
Canadian dollars	654
Euro	1,042
British pounds	1,235
U.S. dollars	31,150
Total gross trade accounts receivable	$ 34,097

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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. Beginning in 2009, we began foreign currency hedging transactions to partially mitigate our exposure to foreign currency exchange risks. Based on international blood screening product sales during 2008, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $6.4 million annually. Similarly, a 10% movement of currency exchange rates would result in a diagnostic product sales increase or decrease of approximately $2.2 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. We believe that our business operations are not significantly exposed to market risk relating to commodity prices.

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-35.

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 Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily 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 also is 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, a control 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 2008.

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.

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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, 2008 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, 2008.

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, 2008. This report, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2008, 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, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Gen-Probe Incorporated s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, Gen-Probe Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, 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, 2008 and 2007, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2008 and our report dated February 17, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 17, 2009

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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 our Proxy Statement to be filed in connection with our 2009 Annual Meeting of Stockholders (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 our 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 our Proxy Statement.

Information regarding our equity compensation plans is incorporated in this report by reference from our 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 our Proxy Statement.

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

The information required by this Item is incorporated in this report by reference from our 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, 2008 and 2007

Consolidated Statements of Income for each of the three years in the period ended December 31, 2008

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2008

Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2008

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, 2008

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/ Henry L. Nordhoff
Henry L. Nordhoff
Chairman and Chief Executive Officer

Date: February 25, 2009

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/ Henry L. Nordhoff Henry L. Nordhoff	Chairman and Chief Executive Officer (Principal Executive Officer)	February 25, 2009
/s/ Herm Rosenman Herm Rosenman	Senior Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2009
/s/ John W. Brown John W. Brown	Director	February 25, 2009
/s/ Raymond V. Dittamore Raymond V. Dittamore	Director	February 25, 2009
/s/ Armin M. Kessler Armin M. Kessler	Director	February 25, 2009
/s/ John C. Martin John C. Martin, Ph.D	Director	February 25, 2009
/s/ Phillip M. Schneider Phillip M. Schneider	Director	February 25, 2009

/s/ Lucy Shapiro Lucy Shapiro, Ph.D.	Director	February 25, 2009
/s/ Abraham D. Sofaer Abraham D. Sofaer	Director	February 25, 2009

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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, 2008 and 2007, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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, 2008, 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 17, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 17, 2009

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GEN-PROBE INCORPORATED

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

	December 31, 2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,122	$ 75,963
Short-term investments	445,056	357,531
Trade accounts receivable, net of allowance for doubtful accounts of $700 and $719 at December 31, 2008 and 2007, respectively	33,397	32,678
Accounts receivable other	2,900	11,044
Inventories	54,406	48,540
Deferred income tax short term	7,269	8,825
Prepaid income tax	2,306	2,390
Prepaid expenses	15,094	17,505
Other current assets	6,135	4,402
Total current assets	626,685	558,878
Property, plant and equipment, net	141,922	129,493
Capitalized software, net	13,409	15,923
Goodwill	18,621	18,621
Deferred income tax long term	12,286	7,942
License, manufacturing access fees and other assets, net	56,608	58,196
Total assets	$ 869,531	$ 789,053
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 16,050	$ 11,777
Accrued salaries and employee benefits	25,093	20,997
Other accrued expenses	4,027	4,024
Income tax payable		846
Deferred revenue short term	1,278	2,836
Total current liabilities	46,448	40,480
Non-current income tax payable	4,773	3,958
Deferred income tax long term	55	75
Deferred revenue long term	2,333	4,607
Deferred compensation plan liabilities	2,162	1,893
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, 52,920,971 and 53,916,298 shares issued and outstanding at December 31, 2008 and 2007, respectively	5	5
Additional paid-in capital	382,544	415,229
Accumulated other comprehensive income	3,055	1,604
Retained earnings	428,156	321,202
Total stockholders equity	813,760	738,040
Total liabilities and stockholders equity	$ 869,531	$ 789,053

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GEN-PROBE INCORPORATED

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

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Product sales	$ 429,220	$ 370,877	$ 325,307
Collaborative research revenue	20,581	16,619	15,937
Royalty and license revenue	22,894	15,518	13,520
Total revenues	472,695	403,014	354,764
Operating expenses:			
Cost of product sales	128,029	119,641	103,882
Research and development	101,099	97,144	84,545
Marketing and sales	45,850	39,928	37,096
General and administrative	52,322	47,007	44,936
Total operating expenses	327,300	303,720	270,459
Income from operations	145,395	99,294	84,305
Other income/(expense):			
Interest income	16,801	12,772	8,301
Other income/(expense)	(1,333)	(469)	388
Total other income, net	15,468	12,303	8,689
Income before income tax	160,863	111,597	92,994
Income tax expense	53,909	25,457	33,496
Net income	$ 106,954	$ 86,140	$ 59,498
Net income per share:			
Basic	$ 1.99	$ 1.63	$ 1.15
Diluted	$ 1.95	$ 1.58	$ 1.12
Weighted average shares outstanding:			
Basic	53,708	52,975	51,538
Diluted	54,796	54,522	53,101

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2008	2007	2006
Operating activities			
Net income	$ 106,954	$ 86,140	$ 59,498
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	34,715	34,159	27,496
Amortization of premiums on investments, net of accretion of discounts	6,908	4,576	3,204
Stock-based compensation charges	20,663	19,651	23,723
Stock option income tax benefits	3,276	2,596	191
Excess tax benefit from employee stock options	(2,493)	(14,606)	(9,187)
Gain on sale of investment in MPI	(1,600)		
Loss on property and equipment dispositions and other	55	703	99
Impairment of long-lived assets	5,086		
Changes in assets and liabilities:			
Trade and other accounts receivable	7,421	(16,180)	6,544
Inventories	(5,367)	3,588	(7,798)
Prepaid expenses	2,325	(6,141)	(595)
Other current assets	(1,260)	(2,307)	1,683
Other long term assets	(173)	(1,131)	(2,147)
Accounts payable	4,377	(1,818)	(471)
Accrued salaries and employee benefits	4,125	4,273	2,063
Other accrued expenses	101	679	(27)
Income tax payable	(499)	(397)	9,970
Deferred revenue	(3,831)	2,855	(7,516)
Deferred income tax	(2,788)	(7,621)	(6,559)
Deferred rent	(10)	(118)	(112)
Deferred compensation plan liabilities	268	683	961
Net cash provided by operating activities	178,253	109,584	101,020
Investing activities			
Proceeds from sales and maturities of short-term investments	105,994	140,988	132,657
Purchases of short-term investments	(198,691)	(298,824)	(149,012)
Purchases of property, plant and equipment	(39,348)	(23,096)	(50,760)
Purchase of intangible assets, including license and manufacturing access fees	(11,970)	(2,213)	(11,460)
Proceeds from sale of investment in MPI	4,100		
Other assets	27	(279)	(633)

Net cash used in investing activities	(139,888)	(183,424)	(79,208)
Financing activities			
Excess tax benefit from employee stock options	2,493	14,606	9,187
Repurchase and retirement of restricted stock for payment of taxes	(1,529)	(1,474)	(429)
Repurchases of common stock	(74,970)		
Proceeds from issuance of common stock	20,472	48,680	24,395
Net cash (used in) / provided by financing activities	(53,534)	61,812	33,153
Effect of exchange rate changes on cash and cash equivalents	(672)	86	612
Net (decrease) increase in cash and cash equivalents	(15,841)	(11,942)	55,577
Cash and cash equivalents at the beginning of year	75,963	87,905	32,328
Cash and cash equivalents at the end of year	$ 60,122	$ 75,963	$ 87,905
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 3	$	$ 63
Cash paid for taxes	$ 54,783	$ 32,208	$ 29,958

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(In thousands)

	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders Equity
Balance at December 31, 2005	51,138	$ 5	$ 281,907	$ (5,951)	$ (1,231)	$ 172,643	$ 447,373
Deferred compensation related to adoption of SFAS No. 123(R)			(5,951)	5,951			
Cumulative effect adjustment, net of income taxes of $2,583, upon adoption of SAB No. 108						3,883	3,883
Common shares issued from exercise of stock options	913		20,909				20,909
Purchase of common shares through employee stock purchase plan	81		3,486				3,486
Purchase of common shares by board members	3		139				139
Issuance of restricted stock awards	123						
Cancellation of restricted stock awards	(15)		(59)				(59)
Repurchase and retirement of restricted stock for employee taxes	(9)		(429)				(429)
Stock-based compensation expense restricted stock			2,382				2,382
Stock-based compensation expense all other			21,261				21,261
Stock-based compensation, net capitalized to inventory			1,161				1,161
Stock option income tax benefits			9,378				9,378
Comprehensive income:							
Net income						59,498	59,498
Unrealized gains on short-term investments, net					251		251

of income taxes of $111							
Foreign currency translation adjustment					975		975
Comprehensive income							60,724
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 shares issued from exercise of stock options	1,539		45,129				45,129
Purchase of common shares through employee stock purchase plan	74		3,550				3,550
Purchase of common shares by board members	2		128				128
Issuance of restricted stock awards	132						
Issuance of deferred issuance restricted stock awards	20						
Cancellation of restricted stock awards	(61)		(349)				(349)
Repurchase and retirement of restricted shares for employee taxes	(24)		(1,474)				(1,474)
Stock-based compensation expense			19,455				19,455
Stock option income tax benefits			14,606				14,606
Comprehensive income:							
Net income						86,140	86,140
Unrealized gains on short-term investments, net of income taxes of $1,196					2,175		2,175
Foreign currency translation adjustment					(566)		(566)
Comprehensive income							87,749
Balance at December 31, 2007	53,916	$ 5	$ 415,229	$	$ 1,604	$ 321,202	$ 738,040
Common shares issued from exercise of stock options	525		16,771				16,771
Repurchase and retirement of common shares	(1,705)		(74,970)				(74,970)
Purchase of common shares through employee stock purchase plan	98		3,701				3,701

Purchase of common shares by board members	3		148				148
Issuance of restricted stock awards	123						
Issuance of deferred issuance restricted stock awards	20						
Cancellation of restricted stock awards	(32)		(297)				(297)
Cancellation and retirement of restricted shares for employee taxes	(27)		(1,529)				(1,529)
Stock-based compensation expense			20,998				20,998
Stock option income tax benefits			2,493				2,493
Comprehensive income:							
Net income						106,954	106,954
Unrealized gains on short-term investments, net of income tax benefits of $935					1,735		1,735
Foreign currency translation adjustment					(284)		(284)
Comprehensive income							108,405
Balance at December 31, 2008	52,921	$ 5	$ 382,544	$	$ 3,055	$ 428,156	$ 813,760

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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 engaged in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for screening donated human blood. The Company also develops and manufactures nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. The Company has 26 years of research and development experience in nucleic acid detection, and its products, which are based on the Company s patented nucleic acid testing (NAT) technologies, are used daily in clinical laboratories and blood collection centers throughout the world.

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales & Service, Inc., Gen-Probe International, Inc., Gen-Probe UK Limited (GP UK Limited), Gen-Probe Italia S.r.l., Gen-Probe Deutschland GmbH and Molecular Light Technology Limited (MLT) and MLT s subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

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

Foreign currencies

The functional currency for the Company s wholly owned subsidiaries GP UK Limited and MLT and its subsidiaries is the British pound. The functional currency of Gen-Probe Italia SRL and Gen-Probe Deutschland GmbH is the Euro. Accordingly, balance sheet accounts of these subsidiaries are translated into United States dollars using the exchange rate in effect at the balance sheet date, and revenues and expenses are translated using the average exchange rates in effect during the period. The gains and losses from foreign currency translation of the financial statements of these subsidiaries are recorded directly as a separate component of stockholders equity under the caption Accumulated other comprehensive income.

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.

Short-term investments

Short-term investments 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 Interest income.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Realized gains and losses, and declines in value judged to be other-than-temporary on short-term investments, are included in 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 Interest income.

Segment information

The Company identifies its operating segments based on business activities, management responsibility and geographical location. For all periods presented, the Company operated in a single business segment. Revenue by geographic location is presented in Note 12.

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 short-term investments. 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 short-term investments are detailed in Note 4.

Fair value of financial instruments

The carrying value of cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities approximates fair value. See Note 5 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 customer s ability to make payments, additional allowances would be required.

Stock-based compensation

In accordance with Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, 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. The Company has no 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. 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.

Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share, and SFAS No. 123(R). 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 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 from the calculation of diluted net income per share because their effect is anti-dilutive.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table sets forth the computation of net income per share (in thousands, except per share amounts):

	Years Ended December 31,		
	2008	2007	2006
Net income	$ 106,954	$ 86,140	$ 59,498
Weighted average shares outstanding Basic	53,708	52,975	51,538
Effect of dilutive common stock options outstanding	1,088	1,547	1,563
Weighted average shares outstanding Diluted	54,796	54,522	53,101
Net income per share:			
Basic	$ 1.99	$ 1.63	$ 1.15
Diluted	$ 1.95	$ 1.58	$ 1.12

Dilutive securities include stock options and restricted stock subject to vesting. Potentially dilutive securities totaling approximately 2,448,000, 1,556,000, and 1,339,000 for the years ended December 31, 2008, 2007 and 2006, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

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

Product sales also include the sales or rental revenue associated with the delivery of the Company s proprietary integrated instrument platforms that perform its diagnostic assays. Generally, the Company provides its instrumentation to clinical laboratories 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 Company and 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 the Company s technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating, and testing the instrumentation.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company records as collaborative research revenue shipments of its blood screening products in the United States and other countries in which the products have not received regulatory approval. 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 commercial approval, the Company classifies sales of these products as product sales in its consolidated financial statements.

The Company follows the provisions of Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, for multiple element revenue arrangements. EITF Issue No. 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the deliverables in a revenue arrangement constitute separate units of accounting according to the EITF Issue No. 00-21 separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue-recognition policy must be determined for the entire arrangement, and all non-refundable upfront license fees are deferred and recognized as revenues on a straight-line basis over the expected term of the Company s continued involvement in the collaborations.

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 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 sheet.

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

Cost of revenues

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 follows SFAS No. 2, Accounting for Research and Development Costs, in classifying costs between cost of product sales and 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.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shipping and handling expenses

Shipping and handling expenses included in cost of product sales totaled approximately $6,721,000, $5,607,000, and $4,951,000 for the years ended December 31, 2008, 2007 and 2006, 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.

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. The estimated reserve is 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.

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 in accordance with SFAS No. 86, Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed. 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.

Long-lived assets

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

Years

Building	10-39
Machinery and equipment	3-8
Furniture and fixtures	3

Depreciation expense was $26,528,000, $26,592,000, and $21,190,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Amortization of building improvements is provided over the shorter of the remaining life of the lease or estimated useful life of the asset. The costs of purchased intangibles are amortized over their estimated useful lives. See Note 6 for further details of the Company s intangible assets and related amortization expense.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Intangible assets

The Company capitalizes license fee payments that relate to acquired intangibles with alternative future uses in accordance with SFAS No. 2 and SFAS No. 142, Goodwill and Other Intangible Assets.

Consistent with Statement of Financial Accounting Concepts No. 6, Elements of Financial Statements, 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.

In accordance with SFAS No. 142, 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. In accordance with SFAS No. 142, 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

In accordance with SFAS No. 142, the Company does not amortize its goodwill and intangible assets with indefinite useful lives. SFAS No. 142 requires that these assets be reviewed for impairment at least annually. The Company completed its impairment test in the fourth quarter of 2008 and determined that no impairment loss was necessary. If the assets were considered to be impaired, the impairment charge would be the amount by which the carrying value of the assets exceeds the fair value of the assets.

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, periodically and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, the Company performs an impairment analysis to determine if it expects to recover the costs through the subsequent sales of applicable products. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value.

During the year ended December 31, 2008, due to certain indicators of impairment, the Company recorded impairment charges totaling $5,086,000 related to its equity investment in Qualigen, Inc. and its license agreement with Corixa Corporation. Please see Notes 5 and 6, respectively, for a complete discussion of the impairment analysis.

Self-insurance reserves

The Company s consolidated balance sheets at December 31, 2008 and 2007 include approximately $1,858,000 and $1,965,000, 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 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

In accordance with SFAS No. 130, Reporting Comprehensive Income, all components of comprehensive income, including net income, are reported in the financial statements in the period in which they are recognized.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Research and development

Research and development (R&D) costs are accounted for in accordance with SFAS No. 2.

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.

Adoption of recent accounting pronouncements

SFAS No. 157

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, Fair Value Measurements. SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair valued measurements on earnings. SFAS No. 157 applies whenever standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial assets and liabilities in financial statements issued for the Company s fiscal year beginning January 1, 2008. There was no material financial statement impact as a result of adoption.

In accordance with the guidance of FASB Staff Position (FSP) No. 157-2, Effective Date of FASB Statement No. 157, the Company has postponed adoption of the standard for non-financial assets and liabilities that are measured at fair value on a non-recurring basis, until the fiscal year beginning January 1, 2009. The Company does not anticipate

adoption will have a material impact on its consolidated financial position, results of operations or liquidity.

In October 2008, the FASB issued FSP No. 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active. FSP No. 157-3 clarifies the application of SFAS No. 157 in a market that is not active, and is effective as of the issue date, including application to prior periods for which financial statements have not been issued. The Company adopted this statement effective October 10, 2008. There was no material financial statement impact as a result of adoption. See Note 5 for more information.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

SFAS No. 159

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115. SFAS No. 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred (e.g., debt issue costs). The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007.

The Company adopted this statement effective January 1, 2008. During 2008, the Company did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

EITF Issue No. 07-3

In June 2007, the FASB ratified EITF Issue No. 07-3, Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities. EITF Issue No. 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF Issue No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007.

The Company adopted this statement effective January 1, 2008. There was no material financial statement impact as a result of adoption.

Pending adoption of recent accounting pronouncements

SFAS No. 141(R)

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations. SFAS No. 141(R) changes the requirements for an acquirer s recognition and measurement of the assets acquired and liabilities assumed in a business combination, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, in-process research and development and restructuring costs. In addition, under SFAS No. 141(R), changes in an acquired entity s deferred tax assets and uncertain tax positions after the measurement period will impact income tax expense. This statement is effective with respect to business combination transactions for which the acquisition date is after December 31, 2008.

SFAS No. 160

In December 2007, the FASB issued SFAS No. 160, Non-controlling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin No. 51). SFAS No. 160 requires that non-controlling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the non-controlling interest be separately identified in the income statement, that changes in a parent s ownership interest while the parent retains its controlling interest be accounted for as equity transactions, and that any retained non-controlling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value. This statement is effective for fiscal years beginning after December 31, 2008, and shall be applied prospectively.

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However, the presentation and disclosure requirements of SFAS No. 160 are required to be applied retrospectively for all periods presented. The retrospective presentation and disclosure requirements of this statement will be applied to any prior periods presented in financial statements for the fiscal year ending December 31, 2009, and later periods during which we have a consolidated subsidiary with a non-controlling interest. As of December 31, 2008, the Company does not have any consolidated subsidiaries in which there is a non-controlling interest.

EITF Issue No. 07-1

In November 2007, the FASB ratified EITF Issue No. 07-1, Accounting for Collaborative Agreements Related to the Development and Commercialization of Intellectual Property. EITF Issue No. 07-1 defines collaborative agreements as a contractual arrangement in which the parties are active participants to the arrangement and are exposed to the significant risks and rewards that are dependent on the ultimate commercial success of the endeavor. Additionally, it requires that revenue generated and costs incurred on sales to third parties as it relates to a collaborative agreement be recognized as gross or net based on EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent. Essentially, this requires the party that is identified as the principal participant in a transaction to record the transaction on a gross basis in its financial statements. It also requires payments between participants to be accounted for in accordance with already existing generally accepted accounting principles, unless none exist, in which case a reasonable, rational, consistent method should be used. The Company will adopt this guidance effective January 1, 2009 for all collaboration agreements existing as of that date. The Company does not believe adoption will have a material impact on its financial statements, as it believes all agreements are currently in compliance with this standard.

Note 2 Stock-based compensation

In accordance with SFAS No. 123(R), Share-Based Payment, 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. The Company has no 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 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.

The Company used the following weighted average assumptions (annualized percentages) to estimate the fair value of options granted and the shares purchasable under the Company s stock option plans and Employee Stock Purchase Plan (ESPP):

	Stock Option Plans			ESPP		
	2008	2007	2006	2008	2007	2006

Risk-free interest rate	3.0%	4.6%	4.8%	3.3%	5.0%	4.4%
Volatility	34%	36%	42%	34%	29%	40%
Dividend yield						
Expected term (years)	4.2	4.2	4.5	0.5	0.5	0.5
Resulting average fair value	$ 18.36	$ 21.44	$ 20.75	$ 13.31	$ 12.88	$ 12.76

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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 of future dividend payouts. 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. SFAS No. 123(R) requires forfeitures to be 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, 2008
Options	1.4	$ 37,381
ESPP	0.2	91
Restricted Stock	1.9	12,798
Deferred Issuance Restricted Stock	1.5	2,349
		$ 52,619

The following table summarizes the stock-based compensation expense that the Company recorded in its consolidated statements of income in accordance with SFAS No. 123(R) (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Cost of product sales	$ 2,495	$ 3,144	$ 2,337
Research and development	6,101	5,020	8,048
Marketing and sales	2,854	2,404	2,905
General and administrative	9,213	9,083	10,433

Total	$ 20,663	$ 19,651	$ 23,723

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 3 Balance sheet information

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

Inventories

	December 31, 2008	2007
Raw materials and supplies	$ 8,529	$ 7,774
Work in process	24,945	23,829
Finished goods	20,932	16,937
	$ 54,406	$ 48,540

Property, plant and equipment

	December 31, 2008	2007
Land	$ 18,804	$ 13,862
Building	80,426	69,946
Machinery and equipment	153,211	139,871
Building improvements	34,592	32,614
Furniture and fixtures	16,270	16,146
Construction in-progress	19	181
Property, plant and equipment (at cost)	303,322	272,620
Less accumulated depreciation and amortization	(161,400)	(143,127)
Property, plant and equipment (net)	$ 141,922	$ 129,493

Other accrued expenses

	December 31, 2008	2007
Royalties	$ 985	$ 563
Professional fees	1,494	1,145

Warranty	923	2,296
Other	625	20
	$ 4,027	$ 4,024

Note 4 Short-term investments

The Company s short-term investments include tax advantaged municipal securities with a minimum Moody s credit rating of A3 and a minimum Standard & Poor s credit rating of A-. As of December 31, 2008, 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, 2008, the Company s portfolios had an average term of three years and an average credit quality of AA3 as defined by Moody s.

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The following is a summary of short-term investments as of December 31, 2008 and 2007 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2008				
Municipal securities	$ 440,070	$ 6,779	$ (1,793)	$ 445,056
December 31, 2007				
Municipal securities	$ 355,216	$ 2,448	$ (133)	$ 357,531

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2008, by contractual maturity, are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Maturities				
Within one year	$ 91,598	$ 770	$	$ 92,368
After one year through five years	338,766	5,807	(1,793)	342,780
After five through ten years	9,706	202		9,908
Ten years and thereafter				
Total short-term investments	$ 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 Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2008				
Municipal securities	$ 56,174	$ (628)	$ 17,606	$ (1,165)
December 31, 2007				

Municipal securities	$ 26,199	$ (52)	$ 29,439	$ (81)

The net unrealized losses on the Company s investments in municipal securities were primarily caused by market forces resulting from a recent and significant sell off of securities by large holders, such as insurance companies and financial institutions, as they were forced to increase their cash reserve positions. Yields for high-quality short-term municipal paper have risen, which have negatively impacted the Company s portfolios, which have an average term of three years. The Company s current valuation is related to this liquidity impact and is not based on the credit worthiness of the securities held by the Company. 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 investment. 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, 2008 since the Company has the ability and intent to hold those investments until a recovery of fair value, which may be at maturity. Gross realized gains from the sale of short-term investments were $1,142,000, $0, and $260,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Gross

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realized losses from the sale of short-term investments were $133,000, $274,000, and $130,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

Note 5 Fair value measurements

The Company adopted SFAS No. 157 effective January 1, 2008 for financial assets and liabilities measured at fair value. SFAS No. 157 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 the Company s 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 the Company 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.

Following is a description of the Company s 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.

Assets and liabilities measured at fair value on a recurring basis:

The Company s available-for-sale securities are comprised of tax advantaged municipal securities 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table presents the financial instruments carried at fair value, by caption on the consolidated balance sheets and by SFAS No. 157 valuation hierarchy (as described above) as of December 31, 2008 (in thousands):

	Fair Value Measurements at December 31, 2008			
	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
Cash and cash equivalents	$ 15,476	$ 4,602	$	$ 20,078
Short-term investments		445,056		445,056
Total assets at fair value	$ 15,476	$ 449,658	$	$ 465,134

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

Certain assets and liabilities are measured at fair value on a non-recurring basis and therefore are not included in the table above. Items valued using such internally generated valuation techniques are classified according to the lowest level input or value driver that is significant to the valuation. Thus, an item may be classified as Level 3 even though there may be some significant inputs that are readily observable. 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 private company

In 2006, the Company invested in Qualigen, Inc. (Qualigen), a private company. 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 valued initially 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. The Company s investment in Qualigen, which totaled approximately $5,404,000 as of December 31, 2008, is included in License, manufacturing access fees and other assets, net on the consolidated balance sheets.

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 impact on its results of operations.

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, with the consultation and assistance of a third party valuation company, and the support of Qualigen management, the Company performed a valuation

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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 between $4,172,000 and $6,609,000. 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 of Qualigen was valued at approximately $5,404,000. The Company believes that the decline in the value of this investment from its initial cost basis was an other-than-temporary impairment of our investment and thus it recorded an impairment charge of $1,589,000 to write down the carrying value of its equity interest. This amount is included in Other income/(expense) on the consolidated statements of income.

Note 6 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 6 years at December 31, 2008). The Company s intangible and other assets and related accumulated amortization consisted of the following (in thousands, except number of years):

	Weighted Average Amortization Period (Years)	December 31, 2008 Gross	2008 Accumulated Amortization	2008 Net	2007 Gross	2007 Accumulated Amortization	2007 Net
Intangible and other assets:							
Capitalized software	10	$ 25,142	$ 11,733	$ 13,409	$ 25,142	$ 9,219	$ 15,923
Goodwill[1]	N/A	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621
License, manufacturing access fees and other assets:							
Investment in Molecular Profiling Institute, Inc.	N/A				2,500		2,500
Investment in Qualigen, Inc.[2]	N/A	5,404		5,404	6,993		6,993
Patents	8	18,093	16,817	1,276	17,304	16,286	1,018
Purchased intangible assets	20	33,636	33,338	298	33,636	33,002	634
License and manufacturing access fees[3]	10	64,507	18,488	46,019	53,326	10,186	43,140
Other assets	N/A	3,611		3,611	3,911		3,911

$ 125,251	$ 68,643	$ 56,608	$ 117,670	$ 59,474	$ 58,196

(1) In accordance with SFAS No. 142, goodwill is no longer amortized.

(2) The change in the Company s investment in Qualigen is due to an impairment charge of $1,589,000 recorded during the year ended December 31, 2008. See Note 5 for a complete discussion of the impairment analysis.

(3) The Company recorded an impairment charge for the net capitalized balance of $3,496,000 under its license agreement with Corixa Corporation. See complete discussion below.

In January 2008, Caris Diagnostics completed the acquisition of Molecular Profiling Institute, Inc. Pursuant to this sale transaction, the Company s equity interest in Molecular Profiling was converted into approximately $4,400,000 of cash proceeds, of which $4,100,000 was received in January 2008 and the remaining $300,000 was placed into an escrow fund established to satisfy the Company s pro-rata share of indemnification obligations under the Caris/Molecular Profiling merger agreement. The Company recorded a $1,600,000 gain associated with the initial $4,100,000 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

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CE-marked APTIMA HPV assay in Europe, the Company paid Roche $10,000,000 in manufacturing access fees. Prior to and including May 2008, the Company s original payment to Roche of $20,000,000 was being amortized to R&D expense. Beginning in June 2008, the additional payment of $10,000,000 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 $3,496,000 under its license agreement with Corixa Corporation. This charge is included in R&D expense on the consolidated statements of income. Under the license agreement, the Company was granted exclusive rights to several licenses and pending patents, including AMACR, to develop, manufacture and sell in-vitro, nucleic acid and antibody-based assays for the prostate cancer market. The amount of license fees paid to Corixa was initially capitalized based on the Company s assessment at that time of the alternative future uses of the assets, including the Company s initial intent to commercialize the AMACR marker. The Company retains the right to sublicense any of the markers acquired. The Corixa intellectual property was being amortized to R&D expense based upon the estimated life of the underlying patents acquired. 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 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, 2008, the Company had capitalized $13,409,000, net, in software costs associated with development of the TIGRIS instrument.

The Company had aggregate amortization expense of $8,187,000, $7,567,000, and $6,272,000 for the years ended December 31, 2008, 2007 and 2006, respectively, including $2,514,000 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 Ended December 31,		Amortization Expense
2009	$	8,061
2010		7,610
2011		7,563
2012		7,475
2013		7,407
Thereafter		22,886
Total	$	61,002

Note 7 Long-term debt

The Company has an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2009, under which the Company may borrow up to $10,000,000, subject to a borrowing base formula, at the bank s prime rate, or at LIBOR plus 1.0%. At December 31, 2008, the Company did not have any amounts outstanding under the bank line and the Company has not taken advances against the line of credit since its inception. The Company was in compliance with all of the financial and restrictive covenants required by the line of credit agreement at December 31, 2008.

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Note 8 Income tax

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

	Years Ended December 31,		
	2008	2007	2006
United States	$ 160,509	$ 109,431	$ 91,297
Rest of World	354	2,166	1,697
	$ 160,863	$ 111,597	$ 92,994

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

	Years Ended December 31,		
	2008	2007	2006
Current:			
Federal	$ 48,758	$ 31,243	$ 37,225
Rest of World	(6)	541	300
State	9,941	1,826	1,999
	58,693	33,610	39,524
Deferred:			
Federal	(4,831)	(7,816)	(7,821)
Rest of World	79	(26)	(58)
State	(32)	(311)	1,851
	(4,784)	(8,153)	(6,028)
	$ 53,909	$ 25,457	$ 33,496

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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, 2008	2007
Deferred tax assets:		
Research and other tax credit carry-forwards	$ 1,808	$ 3,092
Other intangibles	1,433	
Inventory reserves and capitalization	1,964	3,501
Deferred revenue	1,408	2,881
Deferred compensation	1,754	1,577
Stock compensation	16,529	12,061
Accrued vacation	2,372	2,121
Other accruals and reserves (net)	2,143	1,217
Total deferred tax assets	29,411	26,450
Valuation allowance	(95)	
Total net deferred tax assets	$ 29,316	$ 26,450
Deferred tax liabilities:		
Other intangibles	$	$ (1,123)
Capitalized costs expensed for tax purposes	(5,681)	(6,901)
Depreciation	(2,390)	(924)
Unrealized gains on short-term investments	(1,745)	(810)
Total deferred tax liabilities	(9,816)	(9,758)
Net deferred tax assets	$ 19,500	$ 16,692

At December 31, 2008, the Company also had California research and development credit carry-forwards of approximately $2,782,000, 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.

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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,					
	2008		2007		2006	
Expected income tax provision at federal statutory rate	$ 56,302	35%	$ 39,059	35%	$ 32,548	35%
State income tax provision, net of federal benefit	7,275	5%	4,628	4%	3,850	4%
Tax exempt interest income	(5,210)	(3)%	(3,453)	(3)%	(1,981)	(2)%
Domestic manufacturing tax benefits	(2,920)	(2)%	(1,521)	(1)%	(788)	(1)%
Research tax credits	(1,591)	(1)%	(1,911)	(2)%	(1,319)	(2)%
Settlements with tax authorities	(979)	(1)%	(11,145)	(10)%		0%
Other, net	1,032	1%	(200)	0%	1,186	2%
Actual income tax provision	$ 53,909	34%	$ 25,457	23%	$ 33,496	36%

Effective January 1, 2007, the Company adopted FASB Interpretation No. 48 (FIN 48). The following is a reconciliation of the cumulative unrecognized tax benefits:

Unrecognized tax benefits as of January 1, 2007 (including the cumulative effect increase)	$ 17,512
Decrease in unrecognized tax benefits for years prior to 2007	(289)
Increase in unrecognized tax benefits for 2007	1,189
Decrease in unrecognized tax benefits for settlements with tax authorities during 2007	(13,766)
Decrease in unrecognized tax benefits for lapse of statute of limitations	(43)
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	$ 5,753

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 twelve months.

It is the Company s practice to include interest and penalties that related to income tax matters as a component of income tax expense. Including the cumulative effect of adopting FIN 48, $397,000 of interest and $0 of penalties were

accrued as of January 1, 2008. As of December 31, 2008, the accrued interest balance was $455,000.

Material filings subject to future examination are the Company s federal tax returns for the 2006 and 2007 tax years and its California tax returns for the 2005, 2006 and 2007 tax years.

Tax benefits of $2,493,000, $14,606,000, and $9,378,000 for the years ended December 31, 2008, 2007 and 2006, respectively, related to employee stock compensation programs were credited to stockholders equity.

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Note 9 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.

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 and stock appreciation rights. 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 available for issuance under the amended 2003 Plan are reduced by two shares for each share of restricted stock granted under the 2003 Plan after May 17, 2006 (in lieu of a reduction of one share under the 2003 Plan prior to its amendment).

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 1/48 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):

			Weighted

	Number of Shares	Weighted Average Exercise Price	Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	5,518	$ 40.86		
Granted	950	58.30		
Exercised	(525)	31.95		
Cancelled	(286)	50.32		
Outstanding at December 31, 2008	5,657	$ 44.12	5.4	$ 32,961
Exercisable at December 31, 2008	3,568	$ 37.05	5.0	$ 32,654

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The Company defines in-the-money options at December 31, 2008 as options that had exercise prices that were lower than the $42.84 closing market price of its common stock at that date. The aggregate intrinsic value of options outstanding at December 31, 2008 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 2,317,000 shares that were in-the-money at that date. The total intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was $12,264,000, $45,717,000, and $26,651,000, 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, 2007	262	$ 53.36
Granted	146	59.86
Vested and exercised	(82)	50.46
Forfeited	(32)	53.94
Unvested at December 31, 2008	294	$ 57.51

The fair value of the 82,019, 69,846, and 47,013 restricted stock and Deferred Issuance Restricted Stock awards that vested during the years ended December 31, 2008, 2007 and 2006, respectively, was approximately $4,269,000, $3,187,000 and $1,964,000, respectively.

Additional information about stock options outstanding at December 31, 2008 with exercise prices less than or above $42.84 per share, the closing price as of December 31, 2008 is as follows (in thousands, except per share data):

	Exercisable		Unexercisable		Total	
As of December 31, 2008	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
In-the-money	2,208	$ 28.05	109	$ 40.04	2,317	$ 28.62
Out-of-the-money	1,360	51.68	1,980	57.08	3,340	54.88
Total options outstanding	3,568		2,089		5,657	

Shares of common stock available for future grants under all stock option plans were 548,960 at December 31, 2008.

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

	Years Ended December 31,		
	2008	2007	2006
Exercise price equal to the fair value of common stock on the grant date:			
Weighted-average exercise price	$ 58.30	$ 59.11	$ 50.08
Weighted-average option fair value	$ 18.36	$ 21.44	$ 20.54
Exercise price greater than fair value of common stock on the grant date:			
Weighted-average exercise price	$	$	$
Weighted-average option fair value	$	$	$

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, 2008, 2007 and 2006, employees purchased 97,618, 74,337, and 81,356 shares at an average price of $37.91, $47.76, and $42.85 per share, respectively. As of December 31, 2008, a total of 482,978 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 $250,000,000 of the Company s common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. As of December 31, 2008, the Company repurchased and retired approximately 1,705,400 shares under this program at an average price of $43.96 or $75,000,000 in total. When stock is repurchased and retired, the amount paid in excess of par value is recorded to additional paid-in capital.

Note 10 Commitments and contingencies

Lease commitments

The Company leases certain facilities under operating leases that expire at various dates through August 31, 2009. Future minimum payments under these operating leases were $70,000 as of December 31, 2008. In February 2008, the Company completed the acquisition of the facility where it manufactures its blood screening products, which was previously leased.

Rent expense was $486,000, $1,022,000, and $2,172,000 for the years ended December 31, 2008, 2007 and 2006, 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

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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 $9,400,000, to be paid in installments due upon achievement of specified technical milestones, of which the Company expects $4,190,000 to be paid in 2009. As of December 31, 2008, the Company had $712,000 in outstanding purchase orders for the remaining prototype instruments to be purchased in connection with the Development Agreement. In addition, the Company will purchase validation, pre-production and production instruments, at specified fixed transfer prices, that will cost approximately $8,400,000 in the aggregate if it elects to purchase the number of each instrument type it currently expects to purchase. Of the $8,400,000, the Company expects to purchase $3,606,000 in validation and pre-production instruments during 2009. The Company will also purchase production tooling from Stratec at a cost of approximately $1,200,000, $800,000 of which is expected to be spent in 2009.

The Company is obligated to purchase TIGRIS instruments and raw materials used in manufacturing from two key vendors. The minimum combined purchase commitment was approximately $24,110,000 as of December 31, 2008. Of the $24,110,000, $15,910,000 is expected to be used to purchase TIGRIS instruments, of which the Company anticipates that approximately $6,988,000 will be sold to Novartis.

The Company has one third-party manufacturer for each of its instrument product lines. It is dependent on this third-party manufacturer, and this dependence exposes the Company to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs. The Company has no firm long-term commitments from any of its manufacturers to supply products for any specific period, or in any specific quantity, except as may be provided in a particular purchase order.

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 16% 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 $175,000. During 2008, 2007 and 2006, the Company recorded to cost of products sold $5,198,000, $5,020,000, and $3,598,000, respectively, in royalty costs related to its various license agreements.

Litigation

The Company is a party to the following litigation and may be involved in other litigation in the ordinary course of business. 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.

Digene Corporation

In December 2006, Digene Corporation (Digene) filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution of the American Arbitration Association in New York (ICDR). Digene s arbitration demand challenges 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 human papillomavirus (HPV) oligonucleotide products. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting the Company an improper sublicense and seeks a determination that the supply and purchase agreement is null and void.

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On July 13, 2007, the ICDR arbitrators granted the Company s petition to join the arbitration. On August 27, 2007, Digene filed an amended arbitration demand and asserted a claim against the Company for tortious interference with the cross-license agreement. The arbitration hearing in this matter commenced on October 27, 2008 and the presentation of evidence concluded November 10, 2008. In December 2008 and January 2009, the parties filed post-hearing briefs and closing arguments were presented on January 30, 2009.

The Company believes that the supply and purchase agreement is valid and that its purchases of HPV oligonucleotide products under the supply and purchase agreement are and will be in accordance with applicable law. However, there can be no assurance that the matters will be resolved in favor of the Company.

Note 11 Collaborative and license agreements

Novartis (formerly Chiron Corporation)

In June 1998, the Company entered into a collaboration agreement with Chiron (now Novartis) to develop, manufacture and market nucleic acid probe assay systems for the blood screening and clinical diagnostic markets. Under the terms of the collaboration agreement, Novartis or a third party will market and sell products that utilize Novartis intellectual property relating to hepatitis C virus (HCV) and human immunodeficiency virus (type 1) (HIV-1) and the Company s patented technologies. The Company received an up-front license fee of $10,000,000 under the collaboration agreement in 1998. In September 1998, Chiron assigned the clinical diagnostic portion of the collaboration agreement to Bayer (which, in turn, assigned the clinical diagnostics portion of the collaboration agreement to Siemens Healthcare Diagnostics, Inc.).

Under the collaboration agreement, as amended, both Novartis and the Company provide certain access to their intellectual property. The Company has responsibility for research, development and manufacturing of the blood screening products, while Novartis has responsibility for marketing, distribution and service of the blood screening products worldwide. The agreement, as amended, contains the following deliverables from the Company: (i) initial license of the Company s technology, (ii) R&D, and (iii) manufacturing.

The Company determined that the technology license, R&D, and manufacturing were not separate units of accounting, in accordance with EITF Issue No. 00-21. The R&D and manufacturing do not have stand-alone value to Novartis since the related efforts are based on unique technology that could not be obtained from other vendors. Accordingly, the Company has accounted for the elements as follows: (i) initial license payment of the Company s technology is being recognized over the expected development and commercialization term (15 years); (ii) amounts paid to the Company for R&D efforts, representing the reimbursement of costs incurred by the Company, are shared 50/50 with Novartis and are recorded as collaborative research revenue (there is no required minimum obligation for the Company to provide services); and (iii) the Company manufactures the products under the collaboration agreement and shares net revenues of approximately 50/50 (ranging from 45.75% to 50.0%) with Novartis, which support a reasonable margin related to costs of manufacturing. 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.

In January 2009, the Company entered into an agreement (Amendment No. 11) with Novartis to amend the June 11, 1998 collaboration agreement (the 1998 Agreement) between the parties. The effective date of Amendment No. 11 is

January 1, 2009. Amendment No. 11 extends to June 30, 2025 the term of the parties blood screening collaboration under the 1998 Agreement. The 1998 Agreement was scheduled to expire by its terms in 2013. See Note 16 for further discussion of Amendment No. 11.

U.S. blood centers began using the Procleix WNV assay to screen donated blood under an Investigational New Drug (IND) application in June 2003. The Company submitted a Biologics License Application (BLA) for the West Nile virus (WNV) assay to the FDA in February 2005. For the years ended December 31, 2008, 2007 and 2006, the Company recognized $0, $0, and $9,205,000, respectively, in collaborative research revenue through its collaboration with Novartis from deliveries of WNV tests on a cost recovery basis. For the years ended

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December 31, 2008, 2007 and 2006, the Company recognized $0, $355,000, and $1,009,000, respectively in reimbursements for expenses incurred for WNV development research as collaborative research revenue. In early 2006, the Company discontinued recognizing these sales as collaborative research revenue upon first shipment of FDA-approved and labeled product and now records them as product sales.

In March 2003, the Company signed an amendment to the collaboration agreement with Chiron (now Novartis) for the development and commercialization of the Procleix Ultrio assay. During the years ended December 31, 2008, 2007 and 2006, t