GEN PROBE INC
Form 10-K
February 25, 2008

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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, 2007

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. o

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

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

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

As of June 29, 2007, 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 $2.7 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 15, 2008, 53,974,022 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 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, PROGENSA, 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 25 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 also have 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 40 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, through its subsidiary Rebio Gen, Inc., or Rebio Gen, to market products in various overseas markets. We also generate revenues through collaborations with government organizations and 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, 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.

The public may read and copy any materials that we file with the SEC at the SEC s Public Reference Room located at 450 Fifth Street NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains electronic versions of our reports on its website at www.sec.gov.

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

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that detects chlamydia and gonorrhea. Our 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 May 2007, the FDA approved our Procleix TIGRIS system for use with our Procleix Ultrio assay to 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. The system and assay also detect hepatitis B virus, or HBV, in blood donations that are HBV-positive based on serology tests for HBV surface antigen and core antibodies. The system has not been approved at this time to screen donated blood for HBV, as the initial clinical studies were not designed to, and did not, demonstrate HBV yield. Yield is defined as HBV-infected blood donations that were intercepted by the Procleix Ultrio assay, but that were initially negative based on serology tests. We and Novartis have initiated post-marketing studies to demonstrate HBV yield and gain the associated donor screening claim. We believe we have met our goal of identifying two yield cases in the studies, although this must be confirmed through a regulatory submission to the FDA. We filed a supplemental Biologic License Application, or BLA, with the FDA in February 2008 in hopes of gaining a donor screening claim for HBV.

The FDA also approved in 2007 our Procleix TIGRIS system to screen donated blood, organs and tissues for WNV using the Procleix WNV assay. The TIGRIS system can process 1,000 blood samples in about 14 hours. This level of productivity facilitates individual donor testing, which increases screening sensitivity and blood safety. Blood testing sites typically screen for WNV using pooled samples; however, when predetermined WNV prevalence rates occur in the site s geographic area, they switch to individual donor testing.

In April 2007, we entered into an exclusive collaboration agreement with 3M Company, or 3M, to develop and commercialize rapid nucleic acid tests to detect certain dangerous healthcare associated infections, such as methicillin-resistant *Staphylococcus aureus*. Under the terms of the agreement, we are responsible for assay development, which 3M helps fund. 3M is primarily responsible for integrating these assays onto one of its proprietary integrated instrument platforms currently under development. We will conduct bulk manufacturing of assays, while 3M will produce disposables for use on its instrument. 3M will manage clinical trials and regulatory affairs, and will handle global sales and marketing with co-promotion assistance from our sales representatives. 3M has agreed to pay milestones to us based on technical and commercial progress, the first of which was achieved in November 2007, and we will share profits from the sale of commercial products developed under the agreement.

In November 2007, 3M informed us that it no longer intended to fund our separate collaboration entered into in November 2006 to develop rapid molecular assays for the food testing industry. We and 3M subsequently terminated the agreement and we are seeking other opportunities to commercialize our prototype assays in the food testing field. Prior to termination, we achieved certain technical milestones with our assays entitling us to $2.0 million in payments from 3M, which we recognized in the quarter ended December 31, 2007.

Millipore recently launched the first assay developed under our industrial testing collaborations. In January 2008, Millipore commenced commercialization of the first MilliPROBE assay, 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.

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 deoxyribonucleic acid, or 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

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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 six 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 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 focus our business on market opportunities in three segments of the NAT market, clinical diagnostics (including, more recently, cancer diagnostics and the detection of healthcare associated infections), 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 2007. In blood screening, we estimate that currently our 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.

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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. That agreement was terminated in December 2007 and we are seeking other opportunities to commercialize our prototype assays in the food testing field.

The diagram below illustrates 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 currently are 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.*

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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 develop 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.

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, about 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 CDC, an estimated 4.1 million people in the United States have been infected with HCV, of whom 3.2 million are chronically infected. 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 are being discovered at an increasing rate. Our first diagnostic tests are 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 one in six men. We are also developing tests to detect human papillomavirus, or HPVs, which have been recognized as the major cause of 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 or 24 samples. These pooled samples are then tested to determine whether a virus is present. If the presence of a virus is detected, additional

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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.

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 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 individual donor testing, or 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, 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. 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 some blood collection centers will seek to adopt IDT for some or all organisms, 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 individual donor testing.

Demand for improved diagnostic tests for cancer. New markers that correlate to the presence of cancer cells are being discovered at an ever-increasing rate, 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 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

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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.

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.

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 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.

Development of other emerging markets for NAT technology. We believe markets will continue to develop for new applications for 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 anomolies 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, Millipore and 3M using real-time technology. Millipore launched the first such product under our collaboration in January 2008.

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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 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 our Procleix HIV-1/HCV assay. In December 2005, the FDA approved our WNV assay for use on our enhanced semi-automated instrument system, or 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. Our FDA-approved NAT assays currently are performed on our proprietary luminometers and our semi-automated Direct Tube Sampling, or DTS, and TIGRIS (in the case of our APTIMA Combo 2 and WNV assay) instruments. As of December 31, 2007, we had more than 450 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, 2007, our world-class research and development group consisted of 239 full-time employees, 100 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, and our Procleix Ultrio assay that detects HIV-1, HCV and HBV in donated blood, 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. 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.

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

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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 2007 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, 2007, our direct sales force consisted of 40 employees and a 44 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 ten 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 126 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 TUV, a leader in independent testing and assessment services. 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, our Procleix HIV-1/HCV assay, which is currently being used to screen more than an estimated 80% of the United States blood supply.

We are exploring opportunities to develop new products for emerging NAT markets. We recently CE marked our 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. In May 2006, we

entered into a license agreement with the University of Michigan for exclusive worldwide rights to develop diagnostic tests for recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue.

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

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respective collaboration, will enable us to access large customer bases in the markets for industrial-water and biopharmaceutical process testing, respectively. We recently terminated a collaboration with 3M for the development and commercialization of NAT products to enhance food safety, and are currently exploring other opportunities in this field. Prior to termination, we achieved certain technical milestones with our prototype assays entitling us to $2.0 million in payments from 3M.

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 significantly reduces 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 currently are developing a new automated instrument platform designed for low to mid-volume customers as well as other next-generation systems to meet customers needs for increased productivity, automation and point of care or field testing capabilities. Ultimately, 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 are currently developing tests to detect HPV. In addition, we entered into an exclusive collaboration agreement with 3M in April 2007 to develop and commercialize rapid nucleic acid tests to detect certain dangerous healthcare associated infections, such as methicillin-resistant *Staphylococcus aureus*. In June 2007, we entered into a non-exclusive license agreement with Institut Pasteur covering U.S. and foreign patents owned by Institut Pasteur that relate to the detection of vancomycin resistant *enterococcus,* or VRE. We may utilize the VRE license in our collaboration with 3M to develop products in the field of healthcare associated infections.

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 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-approved products to market will reduce 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 historically have 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 December 2004, we entered into a license agreement with Corixa Corporation pursuant to which we received rights to develop molecular diagnostic tests for multiple potential genetic markers in the areas of prostate and other cancers. In December 2005, we entered into a license

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agreement with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. for access to additional markers that we believe can help us to further increase the accuracy of our tests for prostate cancer. Most recently, 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.

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, Millipore and 3M, 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, biopharmaceutical processes and healthcare associated infection testing, respectively.

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;
- chemiluminescent detection using Hybridization Protection Assay and Dual Kinetic Assay technologies; and
- fluorescent real-time detection 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 labeled DNA probes. This is in contrast to most DNA targets, which exist as double strands that must be

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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.

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 target organisms and also remove materials in the sample that might otherwise interfere with amplification.

Target capture offers the following benefits:

Concentration of target organisms 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.

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 for routine clinical laboratory use 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;

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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 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 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 Dual Kinetic Assay, or 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.

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 amplification, with fluorescent probe detection that gives increased fluorescent outputs with increasing amounts of 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.

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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 microorganisms 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.

Clinical Diagnostic Products for the Detection of Non-Viral Microorganisms

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	April 1990	
		Neisseria gonorrhoeae	November 1989	
		Streptococcus pneumoniae	August 1990	
		Staphylococcus aureus	August 1990	
		Listeria monocytogenes	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 also have 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.

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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 six 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 its 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 the latest versions of our core technologies, including target capture, HPA and DKA. 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 80% 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 stand-alone APTIMA assays for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* on the TIGRIS instrument. We

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also have 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.

Clinical Diagnostic Products for the Detection of Viral Microorganisms

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 also have 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.

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Clinical Diagnostic Products for the Detection of Markers for Cancer

PROGENSA PCA3 Assay and ASRs. In November 2006, we CE marked our PCA3 assay, allowing it to be marketed in the European Economic Area. This gene-based test detects the over expression of PCA3 mRNA in urine. Studies have shown that, in greater than 90 percent of prostate cancer cases, PCA3 is 60 to 100-fold over-expressed in prostate cancer cells compared to normal cells, indicating that PCA3 may be a useful biomarker for prostate cancer. DiagnoCure is the exclusive worldwide 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, 2007, 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.

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 plasma, organs and 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)	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 IND filed with the FDA. The American Red Cross is the largest supplier of blood, plasma and tissue products in the United States. The American Red Cross provides almost half of the nation s blood supply through its national network. 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 our Procleix HIV-1/ HCV assay is currently utilized to screen

over 80% of the United States donated blood supply.

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The FDA approved our BLA for the Procleix HIV-1/HCV assay in February 2002. As a result of FDA approval, Novartis began in the second quarter of 2002 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.

As noted above, most blood collection centers currently screen donated blood by taking samples from individual donors and then conducting a probe-based 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. However, we believe that the FDA may ultimately require testing of each unit of donor blood individually. Because of the volume of donated blood, testing all units individually would be impractical without fully automated instrumentation. For this reason, we developed the TIGRIS instrument, which we believe will provide the automation necessary to facilitate individual donor testing.

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. The systems have not been approved at this time to screen donated blood for HBV, as the initial clinical studies were not designed to, and did not, demonstrate HBV yield. Yield is defined as HBV-infected blood donations that were intercepted by the Procleix Ultrio assay, but that were initially negative based on serology tests. We and Novartis have initiated post-marketing studies to demonstrate HBV yield and gain the associated donor screening claim. We believe we have met our goal of identifying two yield cases in the studies, although this must be confirmed through a regulatory submission to the FDA. We filed a supplemental BLA with the FDA in February 2008 in hopes of gaining a donor screening claim for HBV.

On December 1, 2005, the FDA granted marketing approval for our 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 our 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 expanding our offerings in the clinical diagnostics field, we entered into an exclusive collaboration agreement with 3M in April 2007 to develop and commercialize rapid nucleic acid tests to detect certain dangerous healthcare associated infections, such as methicillin-resistant *Staphylococcus aureus*. Under the terms of the agreement, we are responsible for assay development, which 3M helps fund. 3M is primarily responsible for integrating these assays onto one of its proprietary integrated instrument platforms currently under development.

We recently launched the first assay under our industrial testing collaborations. In January 2008, Millipore commenced commercialization of the first MilliPROBE assay, 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

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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. 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.

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 2,000 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.

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.

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 reduces 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 is helping to drive our growth in

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the STD testing market. We intend to develop additional NAT assays that can be performed on the TIGRIS instrument.

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 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, Inc., or 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, 2007, our direct sales force consisted of a staff of 40 sales employees. We also support our sales efforts through a staff of 44 field technical employees. Our sales representatives have an average of approximately 17 years of overall sales experience, with an average of approximately ten 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.

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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.

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 45% of our total revenues in 2007 and 48% of our total revenues in 2006. 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 2007. Various state and city public health agencies accounted for an aggregate of 9% of our total revenues in each of 2007 and 2006. 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) 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.

Under the collaboration agreement, our share of revenues from assays that include a test for HCV is 45.75% of net revenues after deduction of appropriate expenses. For commercial assays that do not test for HCV, such as the WNV assay, each party retains 50% of the net revenues after deduction of appropriate expenses. Novartis is precluded from appointing a third party distributor in the United States to sell these products.

The collaboration agreement has an initial term of 10 years from the first commercial sale of a blood screening assay following FDA approval, which occurred in the first quarter of 2002. The collaboration agreement may be extended by the development of new products under the collaboration agreement, so that it will expire upon the later of the end of the initial term or five years after the first commercial sale of the last new product developed during the initial term. As of December 31, 2007, we believe the collaboration agreement will terminate in 2012 based on the operation of the foregoing clauses. The collaboration agreement can be terminated by a party earlier 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.

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.

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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.

The collaboration agreement provides that Novartis pay us a $10.0 million milestone upon full FDA approval of the Procleix Ultrio assay on the TIGRIS instrument. We believe that this approval may be received in the second half of 2008, however, there can be no assurance that the Procleix Ultrio assay will receive full regulatory approval by the FDA by that time, or at all.

From inception through December 31, 2007, we recognized a total of $828.8 million in revenue under this collaboration agreement and had recorded $3.7 million in deferred license revenues as of December 31, 2007.

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, 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, 2007, we recognized a total of $30.7 million in revenue under our collaboration agreement with Siemens, including $12.0 million in revenue during 2007, $10.3 million of which was the settlement payment we received in January 2007.

In November 2002, we initiated an arbitration proceeding against Bayer in connection with our collaboration. In August 2006, we entered into definitive settlement documentation with Bayer, referred to herein as the Settlement Agreement, 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 payment of $16.4 million on January 31, 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.

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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 DNA 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 will pay $10.0 million within 10 days of the occurrence of certain future commercial events, but not later than December 1, 2008. 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 has been set for October 2008.

On December 8, 2006, we filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a declaratory judgment that the supply and purchase agreement was valid and did not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit us to join the arbitration, the San Diego County Superior Court entered judgment dismissing our complaint.

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 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.

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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 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 ninety days following our acceptance of prototype Panther instruments, we have the right to terminate the agreement on limited, specified conditions, upon thirty 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 eighty 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 eighty days of written notice.

Exclusive Development and Supply Agreement with 3M

In April 2007, we entered into an exclusive collaboration agreement with 3M to develop and commercialize rapid nucleic acid tests to detect certain dangerous healthcare associated infections, such as methicillin-resistant *Staphylococcus aureus*. Under the terms of the agreement, we are responsible for assay development, which 3M helps fund. 3M is primarily responsible for integrating these assays onto one of its proprietary integrated instrument

platforms currently under development. We will conduct bulk manufacturing of assays, while 3M will produce disposables for use on its instrument. 3M will manage clinical trials and regulatory affairs, and will handle global sales and marketing with co-promotion assistance from our sales representatives. 3M has agreed to pay milestones to us based on technical and commercial progress, the first of which was achieved in November 2007, and we will share profits from the sale of commercial products developed under the agreement. The agreement can be

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terminated by either party upon a material breach, in the event there has not been a product launched under the agreement prior to a specified date and upon certain bankruptcy events. In addition, 3M has the right to terminate the agreement after May 1, 2008 upon not less than six months notice provided certain conditions have been satisfied, including the payment of costs to wind-down the collaboration. The recent termination of our agreement with 3M in food testing does not have any effect on this collaboration.

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.

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

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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, 2007, we recognized a total of $3.5 million in revenue under this agreement, including $0.2 million in revenue during 2007. 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, 2007, we recognized a total of $6.5 million in revenue under this agreement, including $1.2 million in revenue during 2007. 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 a 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, 2007, we incurred a total of $8.7 million in expenses under this agreement, including $2.4 million in expenses during 2007. 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

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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.

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 mircrobiology 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, 2007, we incurred a total of $2.2 million in license fees and $0.1 million in milestone payments under this agreement. We anticipate that we will pay up to an additional $0.3 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 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

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addition, we will fund research at the University over the next five years 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 the majority of our anticipated customer base. As of December 31, 2007, we owned more than 450 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. 111 of our current United States utility patents issued from applications filed prior to June 8, 1995. 116 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 16, 2024. 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.

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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 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 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. 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, 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

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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 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 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

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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 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 upon 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 parasite *Trichomonas vaginalis.* The FDA is currently in the process of revising guidelines for ASRs and these guidelines may result in the FDA limiting the types of products that can be sold as ASRs. Some

products that have been marketed as ASRs may need clearance or approval if the FDA revises its guidelines.

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

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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, 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 DNA 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

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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.

Research and Development

As of December 31, 2007, we had 258 full-time and temporary employees in research and development. Our research and development expenses were $97.2 million in 2007, $84.6 million in 2006 and $71.9 million in 2005.

Employees

As of December 31, 2007, we had 987 full-time employees, of whom 208 hold advanced degrees, 239 were in research and development, 126 were in regulatory, clinical and quality systems, 172 were in sales and marketing, 155 were in general and administrative and 295 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, 2007, we had 62 temporary employees.

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 and the sales cycles accurately. In addition, we base our internal projections of our 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.

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 our blood screening products and Siemens to distribute some of our clinical diagnostic products for the detection of viral microorganisms. Commercial product sales to Novartis accounted for 43% of our total revenues for 2007 and 2006. As of December 31, 2007, we believe our collaboration agreement with Novartis will terminate in 2012. The collaboration agreement may be extended by the mutually agreed

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development of new products under the agreement, in which case the agreement will expire upon the later of the end of the original term or five years after the first commercial sale of the last new product developed during the original term.

In February 2001, we commenced an arbitration proceeding against Chiron (now Novartis) in connection with our blood screening collaboration. The arbitration was resolved by mutual agreement in December 2001. In the event that we or Novartis commence arbitration against each other in the future under the collaboration agreement, proceedings could delay or decrease our receipt of revenue from Novartis or otherwise disrupt our collaboration with Novartis, which could cause our revenues to decrease and our stock price to decline.

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 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 a termination of the 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 human immunodeficiency virus 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.

On December 31, 2006, Bayer completed the sale of its diagnostics division to Siemens. We do not know what effect, if any, the sale of Bayer s diagnostics division to Siemens will have on the remaining elements of our collaboration for viral diagnostic products.

We rely upon bioMérieux for distribution of certain of our products in most of Europe, Rebio Gen, Inc. 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, and we are unable to renew or enter into an alternative agreement, or if we elect to distribute new products directly, we will have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to successfully market our products, our product sales will decrease.

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

We rely, to a significant extent, on our corporate collaborators for funding development and for marketing 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.

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The continuation of any of our collaboration agreements depends on their periodic renewal by us and our collaborators. For example, we believe our collaboration agreement with Novartis will terminate in 2012. The collaboration agreement may be extended by the mutually agreed development of new products under the agreement, in which case the agreement will expire upon the later of the end of the original term or five years after the first commercial sale of the last new product developed during the original term. The collaboration agreement is also subject to termination prior to expiration upon a material breach by either party to the agreement.

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.

If our TIGRIS instrument reliability does not meet market expectations, we may be unable to retain our existing customers and attract new customers.

Complex diagnostic instruments such as our TIGRIS instrument typically require operating and reliability improvements following their initial introduction. We have an active in-service reliability improvement program for our TIGRIS instrument. However, this program may not result in the desired improvements in operating reliability of the instrument. Additionally, failure to resolve reliability issues could limit market acceptance of the instrument, adversely affect our reputation, and prevent us from retaining our existing customers or attracting new customers.

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

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

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

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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 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 blood banks and laboratories that have internally developed assays based on PCR technology, Ortho Clinical Diagnostics, a subsidiary of Johnson & Johnson, that markets an HCV antigen assay, and Abbott and Siemens with respect to immunoassay products. In the future, our blood screening products also 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. 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.

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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.

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 may not be able to obtain supplies from replacement suppliers on a timely or cost-effective basis or not at all. A reduction or stoppage in supply while we seek a replacement supplier would limit our ability to manufacture our products, which could result in a significant reduction in sales and profitability. In addition, an impurity or variation from specification in any raw material we receive could significantly delay our ability to manufacture products. Our inventories may not be adequate to meet our production needs during any prolonged 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 DNA oligonucleotides for human papillomavirus 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 the 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. There can be no assurance that these

matters will be resolved in our favor.

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

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is the only manufacturer of our TIGRIS instrument. MGM Instruments, Inc. is the only manufacturer of our LEADER series of luminometers. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have no firm long-term commitments from KMC Systems, MGM Instruments or any of our other manufacturers to supply products to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order. If KMC Systems, MGM Instruments or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its manufacturing operations or becomes insolvent, then instrument shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation. Further, because we place orders with our manufacturers based on forecasts of expected demand for our instruments, if we inaccurately forecast demand, we may be unable to obtain adequate manufacturing capacity or adequate quantities of components to meet our customers delivery requirements, or we may accumulate excess inventories.

We may in the future need to find new contract manufacturers to increase our volumes or to reduce our costs. We may not be able to find contract manufacturers that meet our needs, and even if we do, qualifying a new contract 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 addition, we are 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 the PCA3 gene and for use in the detection of parasite *Trichomonas vaginalis.* The FDA restricts the sale of these products to clinical laboratories certified under CLIA to

perform high complexity testing and also restricts the types of products that can be sold as ASRs. We understand the FDA is in the process of drafting guidelines for ASRs and these guidelines may result in the FDA limiting the types of products that can be sold as ASRs. Should the FDA modify the ASR rules or its interpretation and enforcement of them in a fashion that makes it difficult or impossible for us to market some or all of our products, 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.

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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 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. Our products may be subject to additional recalls in the future. Although none of our past product recalls had a material adverse impact on our business, a future government-mandated recall, or a voluntary recall by us, 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 and individual donor testing.

We currently receive revenues from the sale of our 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 our blood screening assays 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.

The blood screening market is transitioning from pooled testing of large numbers of donor samples to smaller pool sizes and, we expect, will ultimately move to individual donor testing. A greater number of tests will be required for smaller pool sizes and individual donor testing than are now required. Under our collaboration agreement with Novartis, we bear the cost of manufacturing our blood screening assays. The greater number of tests required for smaller pool sizes and individual donor testing 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 the adoption of smaller pool sizes and individual donor testing. 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 and individual donor testing, because we do not know the ultimate selling price that Novartis would charge to the end user.

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

Historically, a limited number of customers has accounted for a significant portion of our total revenues, and we do not have any long-term commitments with these customers, other than our collaboration agreement with Novartis. Revenues from our blood screening collaboration with Novartis accounted for 45% of our total revenues for 2007 and 48% of our total revenues for 2006. 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 2007. Various state and city public health agencies accounted for an aggregate of 9% of our total revenues in each of 2007 and 2006. 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 450 United States and foreign patents covering our products and technologies as of December 31, 2007, 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 16, 2024 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, continuing 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 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 agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their

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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 disputes with third parties. Our patent disputes with Bayer were resolved by settlement agreement in August 2006. In December 2006, Digene Corporation filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution 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 in this matter has been set for October 2008.

On December 8, 2006, we filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a declaratory judgment that the supply and purchase agreement was valid and did not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit us to join the arbitration, the San Diego County Superior Court entered judgment dismissing our complaint.

We hold certain rights in the blood screening and clinical diagnostics fields under patents originally issued to Chiron (now Novartis) covering the detection of HIV. 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 Chiron (now Novartis). The first interference was between Novartis and the National Institutes of Health, or the NIH, and Centocor, Inc., and pertains to Centocor s 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 pertains 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 and NIH/Centocor invented the subject matter at issue prior to Novartis. We are also informed that Novartis has filed actions in the United States District Court for the District of Columbia challenging the decisions of the Patent and Trademark Office. If Novartis does not prevail in the proceedings, Institut

Pasteur or NIH/Centocor may obtain patent rights covering the detection of HIV and those patent rights may cover our HIV tests. There can be no assurances as to the ultimate outcome of this matter.

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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, 2007, we had approximately $222.2 million of long-lived assets, including $15.9 million of capitalized software, net of accumulated amortization, relating to our TIGRIS instrument, goodwill of $18.6 million, a $2.5 million investment in Molecular Profiling Institute, Inc. (which has since been converted into cash in connection with the sale of Molecular Profiling), a $7.0 million investment in Qualigen, Inc., and $48.7 million of capitalized license and manufacturing access fees, patents, purchased intangibles and other long term assets. Additionally, we had $61.6 million of land and buildings, $16.8 million of tenant improvements, $0.2 million of construction in-progress and $50.9 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.

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.

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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 our blood screening and clinical diagnostic products and our TIGRIS instrument. We expect our expense levels to remain high in connection with our research and development as we 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.

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, we may be unable to address gaps in our product offerings or improve our technology, particularly through acquisitions or investments.

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

We must manufacture or have manufactured our products 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 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. For example, we anticipate that we will need to develop closed unit dose assay pouches containing both liquid and dried reagents, which will be a new process for us. 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

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

Our 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 20% of our total revenues for 2007, 22% of our total revenues for 2006 and 21% of our total revenues for 2005. Sales by Novartis of our blood screening products outside of the United States accounted for 77% of our international revenues in each of 2007 and 2006, and 78% in 2005. Novartis has responsibility for the international distribution of our blood screening products. Our sales in France and Japan that were not made through Novartis accounted for 4% of our international sales in 2007 and 5% of our international sales for each of 2006 and 2005.

We encounter risks inherent in international operations. We expect a significant portion of our sales growth, especially with respect to our blood screening products, to come from expansion in international markets. If the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. 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.

We also may have difficulty introducing new products in international markets. For example, we do not believe our blood screening products will be widely adopted in Germany until we are able to offer an assay that screens for hepatitis A virus and parvo B19, as well as HBV, HIV-1 and HCV. When we seek to enter a new international market, we may be dependent on the marketing and sales efforts of our international distributors.

In addition, we anticipate that requirements for smaller pool sizes or ultimately individual donor testing 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.

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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 also may 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 license.

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

Our products and manufacturing processes require access to technologies and materials that may be subject to patents or other intellectual property rights held by third parties. We may discover that we need to obtain additional intellectual property rights in order to commercialize our products. We may be unable to obtain such rights on

commercially reasonable terms or at all, which could adversely affect our ability to grow our business.

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

Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of any one of our management personnel or our inability to identify, attract, retain and

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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. The position of Vice President, Research and Development has been vacant since April 2007.

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.

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.

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, and we may not realize the anticipated benefits of any acquisition, technology license or strategic alliance.

Managing any 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; and
- integrating or completing the development and application of any acquired technologies, 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.

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

We manufacture 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 our 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 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

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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 ERP software system to replace our various legacy systems. As a part of this effort, we are transitioning data and changing 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 estimates we receive from our 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, 2007 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.

On February 1, 2008, we completed the purchase of the facility where we manufacture our blood screening products. We had previously been leasing this facility, which consists of 93,646 square feet, located in San Diego, California, since November 1997. The purchase price was $15.7 million.

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We also lease the following facility:

Leased Facility

Location	Size	Term of Lease
Rehco Facility San Diego, California	6,438 square feet	Lease expires 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, 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 has been set for October 2008.

On December 8, 2006, we filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a declaratory judgment that the supply and purchase agreement was valid and did not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit us to join the arbitration, the San Diego County Superior Court entered judgment dismissing our complaint.

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, 2007.

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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:

2006	High	Low
First Quarter	$ 55.98	$ 44.48
Second Quarter	$ 60.01	$ 46.23
Third Quarter	$ 55.00	$ 46.53
Fourth Quarter	$ 54.54	$ 44.32

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

As of February 15, 2008, there were 7,123 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, 2007	1,304	$ 69.77		$
November 1-30, 2007	5,766	63.05		
December 1-31, 2007				
Total	7,070(1)	$ 64.29		$

(1) During the fourth quarter of 2007, we repurchased and retired 7,070 shares of our common stock, at an average price of $64.29, 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, 2007, we had an aggregate of 241,230 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, 2007 and, with respect to our consolidated balance sheets, at December 31, 2007 and 2006 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, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004, and 2003 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.

	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of income data for the years ended December 31:					
Revenues:					
Product sales	$ 370,877	$ 325,307	$ 271,650	$ 222,560	$ 188,645
Collaborative research revenue	16,619	15,937	25,843	27,122	15,402
Royalty and license revenue	15,518	13,520	8,472	20,025	3,144
Total revenues	403,014	354,764	305,965	269,707	207,191
Operating expenses:					
Cost of product sales	119,641	103,882	83,900	59,908	45,458
Research and development	97,144	84,545	71,846	68,482	63,565
Marketing and sales	39,928	37,096	31,145	27,191	22,586
General and administrative	47,007	44,936	32,107	31,628	23,233
Total operating expenses	303,720	270,459	218,998	187,209	154,842
Income from operations	99,294	84,305	86,967	82,498	52,349
Net income[1]	$ 86,140	$ 59,498	$ 60,089	$ 54,575	$ 35,330
Net income per share:					
Basic	$ 1.63	$ 1.15	$ 1.19	$ 1.10	$ 0.74
Diluted	$ 1.58	$ 1.12	$ 1.15	$ 1.06	$ 0.72
Weighted average shares outstanding:					
Basic	52,975	51,538	50,617	49,429	47,974
Diluted	54,522	53,101	52,445	51,403	49,137
Balance sheet data as of December 31:					
Cash, cash equivalents and short-term investments	$ 433,494	$ 289,913	$ 220,288	$ 193,826	$ 156,306
Working capital	518,408	342,062	262,375	234,202	169,000
Total assets	789,053	623,839	510,236	411,082	324,741
Stockholders equity[2][3]	738,040	570,208	447,373	361,029	270,375

(1) We adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payment, on January 1, 2006. For 2005, 2004 and 2003, net income including pro forma stock-based compensation expense was $45.3 million ($0.86 per diluted share), $41.9 million ($0.82 per diluted share) and $31.0 million ($0.63 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 FASB 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, 2007, 2006 and 2005 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 of 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 25 years of research and development experience in nucleic acid detection, and our products, which are based on our patented nucleic acid testing, or NAT, technologies, are used daily in clinical laboratories and blood collection centers in countries 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 our 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 are responsible for the research, development, regulatory process and manufacturing of our blood screening products, while Novartis is responsible for marketing, sales, distribution and service of those products.

We are currently developing nucleic acid probe-based products that we hope to introduce in the clinical diagnostic, blood screening and industrial microbiology testing markets, including products for the detection of human papillomavirus, or HPV.

Recent Events

Financial Results

Product sales for 2007 were $370.9 million, compared to $325.3 million in 2006, an increase of 14%. Total revenues for 2007 were $403.0 million, compared to $354.8 million in 2006, an increase of 14%. Net income for 2007 was $86.1 million ($1.58 per diluted share), compared to $59.5 million ($1.12 per diluted share) in 2006, an increase of 45%.

Corporate Collaborations

Millipore Corporation, or Millipore, recently launched the first assay developed under our industrial testing collaborations. In January 2008, Millipore commenced commercialization of the first MilliPROBE assay, 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

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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 November 2007, 3M Company, or 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 the agreement and we are seeking other opportunities to commercialize our prototype assays in the food testing field. Prior to termination, we achieved certain technical milestones with our assays entitling us to $2.0 million in payments from 3M, which we recognized in the quarter ended December 31, 2007.

We are 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, we authorized Stratec Biomedical Systems AG, or Stratec, to commence its Phase 2 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.

In April 2007, we entered into an exclusive collaboration agreement with 3M to develop and commercialize rapid nucleic acid tests to detect certain dangerous healthcare associated infections, such as methicillin-resistant *Staphylococcus aureus*. Under the terms of the agreement, we are responsible for assay development, which 3M helps fund. 3M is primarily responsible for integrating these assays onto one of its proprietary integrated instrument platforms currently under development. We will conduct bulk manufacturing of assays, while 3M will produce disposables for use on its instrument. 3M will manage clinical trials and regulatory affairs, and will handle global sales and marketing with co-promotion assistance from our sales representatives. 3M has agreed to pay milestones to us based on technical and commercial progress, the first of which was achieved in November 2007, and we will share profits from the sale of commercial products developed under the agreement.

Licensing

In connection with our research and development efforts, we have various license agreements with unrelated parties that provide us with rights to develop and market products using certain technology and patent rights maintained by the parties. Terms of the various license agreements require us to pay royalties ranging from 1% up to 16% of future sales on products using the specified technology. The agreements generally provide for a term which commences upon execution and continues until expiration of the last patent covering the licensed technology.

Supply and Purchase Agreement

In February 2005, we entered into a supply and purchase agreement with F. Hoffmann-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 DNA 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 agreed to pay $10.0 million within 10 days of the occurrence of certain future commercial events, but not later than December 1, 2008. We also agreed to pay Roche transfer fees for 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 has been set for October 2008.

On December 8, 2006, we filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a

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declaratory judgment that the supply and purchase agreement was valid and did not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit us to join the arbitration, the San Diego County Superior Court entered judgment dismissing our complaint.

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.

Product Development

In May 2007, the Food and Drug Administration, or FDA, approved our Procleix TIGRIS system for use with our Procleix Ultrio assay to 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. The system and assay also detect HBV in blood donations that are HBV-positive based on serology tests for HBV surface antigen and core antibodies. The system has not been approved at this time to screen donated blood for HBV, as the initial clinical studies were not designed to, and did not, demonstrate HBV yield. Yield is defined as HBV-infected blood donations that were intercepted by the Procleix Ultrio assay, but that were initially negative based on serology tests. We and Novartis have initiated post-marketing studies to demonstrate HBV yield and gain the associated donor screening claim. We believe we have met our goal of identifying two yield cases in the studies, although this must be confirmed through a regulatory submission to the FDA. We filed a supplemental Biologic License Application, or BLA, with the FDA in February 2008 in hopes of gaining a donor screening claim for HBV.

The FDA also approved in 2007 our Procleix TIGRIS system to screen donated blood, organs and tissues for WNV using the Procleix WNV assay. The TIGRIS system can process 1,000 blood samples in about 14 hours. This level of productivity facilitates individual donor testing, which increases screening sensitivity and blood safety. Blood testing sites typically screen for WNV using pooled samples; however, when predetermined WNV prevalence rates occur in the site s geographic areas, they switch to individual donor testing.

In January 2007, the United States Army Medical Research and Material Command, which actively manages research programs for the Department of Defense, granted us a $2.5 million award for the development of improved cancer diagnostic assays. In September 2007, this award was increased by $1.1 million to $3.6 million. As of December 31, 2007, we recognized $3.6 million of this grant as collaborative research revenues.

Litigation Settlement

Bayer Corporation (now Siemens Healthcare Diagnostics, Inc.)

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, we dismissed the patent litigation we filed against Bayer and granted Bayer immunity from suit for all current Bayer nucleic acid diagnostic products. We also agreed not to assert four specified patents against future Bayer products. Also, Bayer granted us immunity from suit for our current TIGRIS instrument and agreed not to assert certain specified Bayer patents against our future instruments.

Pursuant to the Settlement Agreement, Bayer paid us an initial license fee of $5.0 million in August 2006. Bayer also 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, 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 to us in the arbitration for qualitative HIV-1 and HCV assays, so that the license would run through the life of the relevant HIV-1

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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.

Revenues

We derive revenues from three primary sources: product sales, collaborative research revenue and royalty and license revenue. The majority of our revenues come from product sales, which consist primarily of sales of our NAT assays tested on our proprietary instruments which serve as the analytical platforms for our assays. We recognize as collaborative research revenue payments we receive from Novartis for the products provided under our collaboration agreement with Novartis prior to regulatory approval, and the payments we receive from Novartis and other collaboration partners for research and development activities. Our royalty and license revenues reflect fees paid to us by third parties for the use of our proprietary technology. In 2007, product sales, collaborative research revenues and royalty and license revenues equaled 92%, 4% and 4%, respectively, of our total revenues of $403.0 million.

Product sales

Our primary source of revenue is 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.

We supply NAT assays for use in screening blood donations intended for transfusion. Our primary blood screening product in the United States detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments 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 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 end-users, less freight, duty and certain other adjustments specified in our collaboration agreement with Novartis, as amended, multiplied by our share of the net revenue. Under our collaboration agreement with Novartis, our share of revenues from assays that include a test for HCV is 45.75% of net revenues after deduction of appropriate expenses. For commercial assays that do not include a test for HCV, such as the WNV assay, each party retains 50% of net revenues after deduction of appropriate expenses. Our costs related to these products after commercialization are primarily manufacturing costs.

Collaborative research revenue

Under our collaboration agreement with Novartis, we have responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Novartis has responsibility for marketing, distribution and service of the blood screening products worldwide.

We have recorded revenues related to use of our blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue because of price restrictions applied to these products prior to FDA license approval in the United States and similar approvals in foreign countries. In December 2005, the FDA granted marketing approval for our WNV assay on our enhanced semi-automated instrument system, or eSAS, to screen donated human blood. In the first quarter of 2006, upon shipment of FDA-approved and labeled product, we began recognizing prospective sales of the WNV assay for use on

eSAS as product sales.

The costs associated with collaborative research revenue are primarily based on fully burdened full time equivalent labor 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

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separately track the costs applicable to collaborations and, therefore, are not able to quantify the direct costs associated with collaborative research revenue.

Royalty and license revenue

We recognize royalty revenue for royalties due to us upon 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 that we have satisfied all performance obligations.

Cost of product sales

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 raw 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 research and development, or R&D, expenses. 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 for the foreseeable future, below its potential capacity. A portion of this available capacity is utilized for development of new product candidates. As a result, certain operating costs of our blood screening 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.

A portion of our blood screening revenues is from sales of TIGRIS instruments to Novartis, which totaled $9.4 million and $9.7 million, during 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 sales of blood screening assays in the future.

Research and development

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 co-development of new products and technologies in collaboration with our partners. R&D spending is expected to increase in the future due to new product development, clinical trial costs and manufacturing costs of development lots; however, we expect our R&D expenses as a percentage of total revenues to decline in future years. The timing of clinical trials and development manufacturing costs is variable and is affected by product development activities and the regulatory process.

In connection with our R&D efforts, we have various license agreements that provide us with rights to develop and market products using certain technologies and patent rights maintained by third parties. These agreements generally

provide for a term that commences upon execution of the agreement and continues until expiration of the last patent covering the licensed technology.

R&D expenses include the costs of raw materials, development lots and clinical trial lots of products that we manufacture. These costs are 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 the manufacture of development lots and clinical trial lots for our blood screening products, further development of our TIGRIS instrument, initial development of a fully automated system for low to mid-volume laboratories, as well as for the

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development of assays to detect human papillomavirus, or HPV, PCA3, healthcare associated infections and for industrial applications.

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 financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, valuation of inventories, long-lived assets, including patent costs and capitalized software, income taxes and 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 our 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. We have also implemented multi-year sales contracts that have an equipment factor set forth in them. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of an instrument, which ranges from three to five years; generally, three years for luminometers and DTS 400/800 instruments, and five years for the TIGRIS instrument and DTS 800/1600 instruments. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

We sell 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. We record sales of these instruments as product sales 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 instrument systems requires installation and training by our technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating, and testing the instrumentation.

We 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 related to the element. Milestone payments are recognized as revenue upon the

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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) our performance obligations after the milestone achievement will continue to be funded by our 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 our balance sheet.

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 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 into 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 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 2007, 2006 and 2005, 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.

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

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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 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, 2007, capitalized software development costs related to products for use on our TIGRIS instrument totaled $15.9 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. During 2007, we recorded an income tax benefit of $11.1 million resulting from the completion of federal and state audits of our tax returns through 2004.

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

Stock-based compensation

We grant options to purchase our common stock to our employees and directors under our equity compensation plans. Eligible employees can also purchase shares of our common stock at 85% of the lower of the fair market value on the first or the last day of each six-month offering period under our Employee Stock Purchase Plan, or ESPP. The benefits provided under these plans are share-based payments subject to the provisions of revised Statement of Financial Accounting Standards No. 123(R), or 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, certain of these costs are capitalized into inventories on our balance sheet, and generally are recognized as an 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-

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Scholes-Merton model, may not provide reliable measures of the fair values of our share-based compensation 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 awards in accordance with SFAS 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. The volatility percentage assumed for 2007 and 2006 was based on a blend of implied and historical volatility data. 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, 2007, we used a weighted average stock price volatility of 36%. If our stock price volatility assumptions were increased to 45%, the weighted average estimated fair value of stock options granted during the year ended December 31, 2007 would increase by $4.28 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, 2007 we used an expected term of 4.2 years. If our expected term were to increase a year to 5.2 years, the weighted average estimated fair value of stock options granted during the year ended December 31, 2007 would increase by $2.65 per share, or 11%.

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.

Adoption of recent accounting pronouncements

Adoption of FIN No. 48

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes an interpretation of SFAS No. 109, or FIN No. 48, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN No. 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. FIN No. 48 is effective for fiscal years beginning after December 15, 2006.

We adopted this statement effective January 1, 2007. In accordance with the transition guidance provided by FIN No. 48, we increased our accrual for unrecognized tax benefits, principally related to research tax credits, by adjusting for the net impact of the change in guidance, which was approximately $1.0 million. The adjustment was accounted for as a reduction in the beginning balance of retained earnings and an increase in the beginning balance of net tax liabilities. 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	$ 4,603

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All of the unrecognized tax benefits, if recognized, would affect our effective tax rate. We do not anticipate there will be a significant change in the unrecognized tax benefits within the next 12 months.

It is our 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 No. 48, $2.2 million of interest and $0 of penalties were accrued as of January 1, 2007. As of December 31, 2007, the accrued interest balance was $0.4 million.

Our federal tax returns for the 2005 and 2006 tax years are currently under examination. Material filings subject to future examination are our California tax returns for the 2005 and 2006 tax years.

Tax benefits of $14.6 million, $9.4 million and $8.7 million for the years ended December 31, 2007, 2006 and 2005, respectively, related to employee stock compensation programs were credited to stockholders equity.

Pending adoption of accounting pronouncements

SFAS No. 157

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, or 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 request 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 statements issued for fiscal years beginning after November 15, 2007. We do not anticipate the adoption of SFAS No. 157 will have a material effect on our consolidated financial position, results of operations or liquidity.

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, or SFAS No. 159. 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. We are currently determining whether fair value accounting is appropriate for any of our eligible items and cannot estimate the impact, if any, that SFAS No. 159 will have on our consolidated financial position, results of operations or liquidity.

EITF No. 07-1

In November 2007, the FASB ratified Issue No. EITF 07-1, Accounting for Collaborative Agreements Related to the Development and Commercialization of Intellectual Property, or EITF Issue No. 07-1. 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. 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. EITF Issue No. 07-1 is effective for fiscal years

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beginning after December 15, 2008 for all collaborative arrangements existing as of that date, with retrospective application to all periods. We do not anticipate the adoption of EITF Issue No. 07-1 will have a material effect on our financial position, results of operations or liquidity.

EITF No. 07-3

In June 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-3, Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF Issue No. 07-3. EITF Issue No. 07-3 requires that nonrefundable 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. We do not anticipate the adoption of EITF Issue No. 07-3 will have a material effect on our consolidated financial position, results of operations or liquidity.

SFAS No. 141(R)

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations, or SFAS No. 141(R). 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, Noncontrolling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin, or ARB, No. 51), or SFAS No. 160. 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, 2007, we do not have any consolidated subsidiaries in which there is a noncontrolling interest.

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Results of Operations

	Years Ended December 31,			% Change	
	2007	2006	2005	2007/2006	2006/2005
	(In millions, except per share data)				
Statement of income:					
Revenues:					
Product sales	$ 370.9	$ 325.3	$ 271.7	14 %	20 %
Collaborative research revenue	16.6	16.0	25.8	4 %	(38)%
Royalty and license revenue	15.5	13.5	8.5	15 %	59 %
Total revenues	403.0	354.8	306.0	14 %	16 %
Operating expenses:					
Cost of product sales	119.6	103.9	83.9	15 %	24 %
Research and development	97.2	84.6	71.9	15 %	18 %
Marketing and sales	39.9	37.1	31.1	8 %	19 %
General and administrative	47.0	44.9	32.1	5 %	40 %
Total operating expenses	303.7	270.5	219.0	12 %	24 %
Income from operations	99.3	84.3	87.0	18 %	(3)%
Total other income, net	12.3	8.7	4.7	41 %	85 %
Income tax expense	25.5	33.5	31.6	(24)%	6 %
Net income	$ 86.1	$ 59.5	$ 60.1	45 %	(1)%
Net income per share					
Basic	$ 1.63	$ 1.15	$ 1.19	42 %	(3)%
Diluted	$ 1.58	$ 1.12	$ 1.15	41 %	(3)%
Weighted average shares outstanding					
Basic	53.0	51.5	50.6		
Diluted	54.5	53.1	52.4		

Amounts and percentages in this table 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.

Product sales

Product sales increased 14% to $370.9 million in 2007 from $325.3 million in 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 our PACE product 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%. Although overall

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dollar values have moved noticeably to APTIMA, overall testing volumes remain more evenly distributed with 60% of the testing volume for STDs on APTIMA and 40% on PACE for 2007. 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, 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 bloodscreening 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.

Product sales increased 20% to $325.3 million in 2006 from $271.7 million in 2005. The $53.6 million increase was primarily attributed to $32.3 million in higher APTIMA assay sales, $23.5 million in higher blood screening assay sales, and $2.7 million in higher instrument sales, partially offset by a $6.6 million decrease in PACE product sales. Revenues from all other product lines increased a combined $1.7 million from 2005. Blood screening related sales, including assay, instrument, and ancillary sales, represented $154.2 million, or 47% of product sales, in 2006, compared to $130.0 million, or 48% of product sales in 2005. The $24.2 million increase in blood screening sales during 2006 was principally attributed to the approval and commercial launch of our WNV assay, as well as international expansion of Procleix Ultrio sales. In 2006, growth of United States blood donation volumes screened using the Procleix HIV-1/HCV assay was relatively flat, 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 22% from 2005 levels, as the Procleix line further penetrated international markets. Diagnostic product sales, including assay, instrument, and ancillary sales, represented $171.2 million, or 53% of product sales, in 2006, compared to $141.6 million, or 52% of product sales in 2005. This 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. In 2006, pricing related to our primary APTIMA products remained consistent with 2005 levels.

We expect increased competitive pressures related to our STD and blood screening products in the future, primarily as a result of the introduction by others of competing products, and continuing pricing pressure as it relates to the STD market.

Collaborative research revenue

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

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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 decreased 38% in 2006 from 2005. The $9.8 million decrease from the prior year was primarily the result of 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 $2.9 million decrease in reimbursements for expenses from Novartis for the Procleix Ultrio assay and WNV assay development research, and the discontinuation of warehousing fees. These decreases were partially offset by a $2.0 million increase in revenue for 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. Under the terms of our collaboration agreement with Novartis, a milestone payment of $10.0 million is due to us in the future if we obtain full FDA approval of our Procleix Ultrio assay for blood screening use on the TIGRIS instrument. Also, milestone payments from 3M are due to us based upon achievement of technological and commercial milestones. There is no guarantee we will achieve these milestones and receive the associated payments under these agreements.

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.

Royalty and license revenue

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 increased 59% in 2006 from 2005. The $5.0 million increase in royalty and license revenue was principally attributed to a $5.0 million increase in license fee revenue from Bayer pursuant to the terms of our settlement agreement, as well as a $1.0 million increase in license revenue from Tosoh as a result of the Bayer settlement expanding the scope of our license agreement with Tosoh.

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

Cost of product sales

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

installed base of instruments ($1.7 million).

Cost of product sales increased 24% in 2006 from 2005. The $20.0 million increase in cost of product sales was primarily due to costs associated with higher blood screening product shipments ($5.3 million, including commercial launch of our WNV assay and international growth of our Procleix Ultrio assay), with increased sales of instruments and spare parts ($5.3 million), higher APTIMA shipments ($4.5 million), an increase in stock-based

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compensation expense ($2.3 million), and higher provisions for scrap related to date expiration of certain oligonucleotide raw material ($1.9 million).

Our gross profit margin as a percentage of product sales remained consistent at 68% in 2007 and 2006, and decreased from 69% in 2005. The similar gross profit margin percentage in 2007 and 2006 was principally attributed to increased instrument amortization and changes in production volume mix, offset by increases in revenue associated with increased sales of APTIMA and commercial sales of the WNV assay. The 2006 percentage decrease from 2005 was primarily the result of increased sales of lower margin products, including TIGRIS instruments and spare parts, higher international sales of blood screening products, which generally have lower margin rates than domestic sales, higher provisions for scrap expense and the addition of stock-based compensation expense.

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.

We anticipate that our blood screening customers requirements for smaller pool sizes or ultimately individual donor testing of blood samples will result in lower gross margin percentages, as additional tests are required to deliver the sample results. We are not able to accurately predict the timing and extent to which our gross margin percentage will be negatively affected as a result of smaller pool sizes or individual donor testing, which depends on associated price changes. 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.

Research and development

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

R&D expenses increased 18% in 2006 from 2005. The $12.7 million increase in R&D spending was primarily due to an increase in stock-based compensation expense ($7.9 million), increases in salaries, benefits, and other personnel related expenses ($2.8 million), higher staffing levels and outside services to support development projects such as industrial applications ($1.5 million), partially offset by a reduction in professional fees ($1.3 million).

Marketing and sales

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

Marketing and sales expenses increased 19% in 2006 from 2005. The $6.0 million increase in marketing and sales expenses was primarily due to an increase in stock-based compensation expense ($2.9 million), higher staffing

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levels to support product sales growth ($1.6 million), and an increase in spending for marketing research and materials ($0.7 million).

General and administrative

Our general and administrative, or G&A, expenses include salaries and personnel-related expenses for finance, legal, strategic planning and business development, public relations and human resources, as well as professional fees for legal, patents and auditing services. G&A expenses increased 5% in 2007 from 2006. The $2.1 million increase in G&A expenses was primarily the result of an increase in salaries, benefits and other personnel related expenses due principally to increased personnel ($5.3 million) and an increase in service contracts due principally to software and equipment upgrades ($0.7 million), offset by a decrease in legal fees ($2.4 million), 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, and a decrease in stock-based compensation expense ($1.3 million) due to increased forfeitures related to employee turnover.

G&A expenses increased 40% in 2006 from 2005. The $12.8 million increase in G&A expenses was primarily the result of an increase in stock-based compensation expense ($9.7 million), an increase in salaries, benefits and other personnel related expenses ($2.1 million) due principally to increased personnel, and an increase in professional fees ($1.0 million) due to higher legal fees associated with our two patent infringement lawsuits against Bayer, including our $2.0 million payment to our outside litigation counsel in connection with the Bayer settlement.

Total other income, net

Total other income, net, generally consists of investment and interest income offset by miscellaneous expense, minority interest, and other items. The $3.6 million net increase 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 and higher yields on our investment portfolio, offset by $0.9 million in realized foreign currency exchange losses.

The $4.0 million net increase in 2006 from 2005 was primarily due to an increase of $3.4 million in interest income resulting from higher average balances of our short-term investments and higher yields on our investment portfolio and $0.5 million in realized foreign currency exchange gains.

Income tax expense

Income tax expense decreased 24% in 2007 from 2006 and our effective tax rate decreased to 22.8% of 2007 pretax income, compared to 36.0% of 2006 pretax income. The decrease in our effective tax rate was principally attributed to 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, as well as higher tax-exempt interest, which impacted our effective tax rate by 10%.

Income tax expense increased 6% in 2006 from 2005 and our effective tax rate increased to 36.0% of 2006 pretax income, compared to 34.5% of 2005 pretax income. The increase in our effective tax rate was principally attributed to lower research and development tax credits, and tax deferred stock compensation expense such as our ESPP, partially offset by benefits from increases in our tax exempt interest income.

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Liquidity and capital resources

	2007	2006	2005	Amount Change From 2006 to 2007
		(In thousands)		
As of December 31:				
Cash, cash equivalents and short-term investments	$ 433,494	$ 289,913	$ 220,288	$ 143,581
Working capital	518,408	342,062	262,375	176,346
Current ratio	14:1	8:1	6:1	
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	$ 109,584	$ 101,020	$ 89,231	$ 8,564
Investing activities	(183,424)	(79,208)	(100,474)	104,216
Financing activities	61,812	33,153	18,696	28,659
Purchases of property, plant and equipment (included in investing activities above)	(23,096)	(50,760)	(45,386)	(27,664)

Historically, we have financed our operations through cash from operations, including cash received from collaborative research agreements, royalty and license fees, and cash from capital contributions. At December 31, 2007, we had $433.5 million of cash and cash equivalents and short-term investments.

The $8.6 million increase in net cash provided by operating activities during 2007 from 2006 was primarily due to higher net income ($26.6 million) and a decrease in inventory levels due to more efficient gross inventory management ($3.6 million), partially offset by an increase in accounts receivable related to several milestone payments earned late in the fourth quarter ($16.2 million) and an increase in prepaid expenses primarily related to increases in prepayments for materials ordered to manufacture TIGRIS instruments ($6.1 million).

The $104.2 million increase in net cash used in investing activities during 2007 from 2006 included a net increase in purchases (net of sales) of short-term investments ($141.5 million), partially offset by a decrease in capital expenditures ($27.7 million), primarily based on completion of the expansion of our headquarters in 2006, and decreased spending on licensed technology ($9.2 million). Our expenditures for capital additions vary based on the stage of certain development projects and may increase in the future related to the timing of development of new product opportunities and to support expansion of our facilities in connection with those opportunities.

The $28.7 million increase in net cash provided by financing activities during 2007 from 2006 was principally attributed to an increase in proceeds from the exercise of stock options ($24.3 million) and an increase in the associated excess tax benefits ($5.4 million). On a going-forward basis, cash from financing activities will continue to be affected by proceeds from the exercise of stock options and receipts from sales of stock under our 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 at LIBOR plus 1.0%. At December 31, 2007, we did not have any amounts outstanding under the bank line and we have not taken advances against the line since inception. The line of credit agreement requires us to comply with various financial and restrictive covenants. As of December 31, 2007, we were in compliance with all covenants.

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Contractual obligations and commercial commitments

Our contractual obligations due for purchase commitments, collaborative agreements and supply agreements as of December 31, 2007 were as follows (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Material purchase commitments[1]	$ 37,580	$ 28,029	$ 7,551	$ 2,000	$
Collaborative commitments[2]	3,391	641	1,800	450	500
Supply agreements[3]	10,000	10,000			
Total[4]	$ 50,971	$ 38,670	$ 9,351	$ 2,450	$ 500

(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 $17.3 million expected to be used to purchase TIGRIS instruments, we anticipate that approximately $12.8 million of these instruments will be sold to Novartis. The development of the Panther instrument includes $11.4 million expected to be used to purchase prototype, validation, pre-production and production instruments, and associated tooling, pursuant to our development agreement with Stratec, 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 corporate collaboration agreements, we may be required to pay up to $10.0 million in milestone payments, plus royalties on net sales of any products using specified technology. We may also be required to pay up to $7.5 million in future development costs in the form of milestone payments.

(3) Amount reflected relates to our obligations under our supply agreement with Roche. We are obligated to pay $10.0 million to Roche upon the occurrence of certain future commercial events, but not later than December 1, 2008.

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

Liabilities associated with uncertain tax positions, currently estimated at $5.0 million (including interest), are not included in the table above as we cannot reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

Additionally, we have liabilities for deferred employee compensation which totaled $3.3 million at December 31, 2007. 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.

Our primary short-term cash needs, which are subject to change, include the acquisition of the facility where we manufacture our blood screening products (which we completed in January 2008), continued R&D spending to support new products, costs related to commercialization of products and purchases of the TIGRIS instrument for placement with our customers. Certain R&D costs may be funded under collaboration agreements with partners.

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 credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to

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covenants restricting our operations. In August 2003, we filed a Form S-3 shelf registration statement with the SEC relating to the possible future sale of up to an aggregate of $150 million of debt or equity securities. To date, we have not raised any funds under this registration statement.

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.

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 $6.8 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 is the British pound. Accordingly, the accounts of these operations are translated from the British pound to the United States dollar using the current exchange rate in effect at the balance sheet date for the balance sheet accounts, and using the average exchange rate during the period for revenue and expense accounts. The effects of translation are recorded in accumulated other comprehensive income as a separate component of stockholders equity.

We are exposed to foreign exchange risk for expenditures in certain foreign countries, but the total receivables and payables denominated in foreign currencies as of December 31, 2007 were not material. 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. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Based on international blood screening product sales during 2007, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.4 million annually. We believe that our business operations are not 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-34.

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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 2007.

Changes in Internal Control Over Financial Reporting

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

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 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, 2007.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Gen-Probe Incorporated

We have audited Gen-Probe Incorporated s internal control over financial reporting as of December 31, 2007, 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, 2007, 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, 2007 and 2006, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2007 and our report dated February 7, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 7, 2008

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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 2008 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, 2007 and 2006

Consolidated Statements of Income for each of the three years in the period ended December 31, 2007

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2007

Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2007

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, 2007

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, President and Chief Executive Officer

Date: February 22, 2008

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, President and Chief Executive Officer (Principal Executive Officer)	February 22, 2008
/s/ Herm Rosenman Herm Rosenman	Senior Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 22, 2008
/s/ John W. Brown John W. Brown	Director	February 22, 2008
/s/ Raymond V. Dittamore Raymond V. Dittamore	Director	February 22, 2008
/s/ Armin M. Kessler Armin M. Kessler	Director	February 22, 2008
/s/ John C. Martin John C. Martin, PH.D	Director	February 22, 2008
/s/ Phillip M. Schneider Phillip M. Schneider	Director	February 22, 2008
/s/ Abraham D. Sofaer	Director	February 22, 2008

Abraham D. Sofaer

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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
Gen-Probe Incorporated

We have audited the accompanying consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2007 and 2006, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, 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.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006 the Company changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment.

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, 2007, 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 7, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 7, 2008

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GEN-PROBE INCORPORATED

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

	December 31 2007	2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 75,963	$ 87,905
Short-term investments	357,531	202,008
Trade accounts receivable, net of allowance for doubtful accounts of $719 and $670 at December 31, 2007 and 2006, respectively	32,678	25,880
Accounts receivable other	11,044	1,646
Inventories	48,540	52,056
Deferred income tax short term	8,825	7,247
Prepaid income tax	2,390	
Prepaid expenses	17,505	11,362
Other current assets	4,402	2,583
Total current assets	558,878	390,687
Property, plant and equipment, net	129,493	134,614
Capitalized software, net	15,923	18,437
Goodwill	18,621	18,621
Deferred income tax long term	7,942	2,064
License, manufacturing access fees and other assets, net	58,196	59,416
Total assets	$ 789,053	$ 623,839
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 11,777	$ 13,586
Accrued salaries and employee benefits	20,997	16,723
Other accrued expenses	4,014	3,320
Income tax payable	846	14,075
Deferred revenue short term	2,836	921
Total current liabilities	40,470	48,625
Non-current income tax payable	3,958	
Deferred income tax long term	75	
Deferred revenue long term	4,607	3,667
Deferred rent	10	128
Deferred compensation plan liabilities	1,893	1,211
Commitments and contingencies		
Stockholders equity:		

Preferred stock, $.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding				
Common stock, $.0001 par value per share; 200,000,000 shares authorized, 53,916,298 and 52,233,656 shares issued and outstanding at December 31, 2007 and 2006, respectively		5		5
Additional paid-in capital		415,229		334,184
Accumulated other comprehensive income (loss)		1,604		(5)
Retained earnings		321,202		236,024
Total stockholders equity		738,040		570,208
Total liabilities and stockholders equity	$	789,053	$	623,839

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Years Ended December 31		
	2007	2006	2005
Revenues:			
Product sales	$ 370,877	$ 325,307	$ 271,650
Collaborative research revenue	16,619	15,937	25,843
Royalty and license revenue	15,518	13,520	8,472
Total revenues	403,014	354,764	305,965
Operating expenses:			
Cost of product sales	119,641	103,882	83,900
Research and development	97,144	84,545	71,846
Marketing and sales	39,928	37,096	31,145
General and administrative	47,007	44,936	32,107
Total operating expenses	303,720	270,459	218,998
Income from operations	99,294	84,305	86,967
Other income/(expense):			
Minority interest			85
Interest income	12,772	8,301	4,852
Interest expense	30	(63)	(162)
Other income/(expense)	(499)	451	(48)
Total other income, net	12,303	8,689	4,727
Income before income tax	111,597	92,994	91,694
Income tax expense	25,457	33,496	31,605
Net income	$ 86,140	$ 59,498	$ 60,089
Net income per share:			
Basic	$ 1.63	$ 1.15	$ 1.19
Diluted	$ 1.58	$ 1.12	$ 1.15
Weighted average shares outstanding:			
Basic	52,975	51,538	50,617
Diluted	54,522	53,101	52,445

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31		
	2007	2006	2005
Operating activities			
Net income	$ 86,140	$ 59,498	$ 60,089
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	34,159	27,496	22,606
Amortization of premiums on investments, net of accretion of discounts	4,576	3,204	3,371
Stock-based compensation charges	19,651	23,723	920
Stock option income tax benefits	2,596	191	8,677
Excess tax benefit from employee stock options	(14,606)	(9,187)	
Loss on disposal of property and equipment	201	99	399
Impairment of fixed assets	502		
Changes in assets and liabilities:			
Accounts receivable	(16,180)	6,544	(8,937)
Inventories	3,588	(7,798)	(9,048)
Prepaid expenses	(6,141)	(595)	(2,251)
Other current assets	(2,307)	1,683	1,797
Other long term assets	(1,131)	(2,147)	(534)
Accounts payable	(1,818)	(471)	7,329
Accrued salaries and employee benefits	4,273	2,063	2,748
Other accrued expenses	679	(27)	(1,089)
Income tax payable	(397)	9,970	12,053
Deferred revenue	2,855	(7,516)	(2,363)
Deferred income tax	(7,621)	(6,559)	(6,717)
Deferred rent	(118)	(112)	(69)
Deferred compensation plan liabilities	683	961	250
Net cash provided by operating activities	109,584	101,020	89,231
Investing activities			
Proceeds from sales and maturities of short-term investments	140,988	132,657	113,536
Purchases of short-term investments	(298,824)	(149,012)	(137,841)
Cash paid for acquisition of Molecular Light Technology Limited			(1,539)
Purchases of property, plant and equipment	(23,096)	(50,760)	(45,386)
Purchase of intangible assets, including license and manufacturing access fees	(2,213)	(11,460)	(29,117)
Other assets	(279)	(633)	(127)
Net cash used in investing activities	(183,424)	(79,208)	(100,474)

Financing activities			
Excess tax benefit from employee stock options	14,606	9,187	
Repurchase and retirement of restricted stock for payment of taxes	(1,474)	(429)	
Proceeds from issuance of common stock	48,680	24,395	18,696
Net cash provided by financing activities	61,812	33,153	18,696
Effect of exchange rate changes on cash and cash equivalents	86	612	(623)
Net (decrease) increase in cash and cash equivalents	(11,942)	55,577	6,830
Cash and cash equivalents at the beginning of year	87,905	32,328	25,498
Cash and cash equivalents at the end of year	$ 75,963	$ 87,905	$ 32,328
Supplemental disclosure of cash flow information:			
Cash paid for:			
Interest	$ 30	$ 63	$ 162
Income taxes	$ 32,208	$ 29,958	$ 16,807

See accompanying notes to consolidated financial statements.

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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, 2004	50,035	$ 5	$ 248,767	$ (1,104)	$ 807	$ 112,554	$ 361,029
Common shares issued from exercise of stock options	890		15,709				15,709
Purchase of common shares through employee stock purchase plan	97		2,987				2,987
Purchase of common shares by board members	4		136				136
Deferred compensation related to grant of restricted stock awards	112		5,631	(5,631)			
Amortization of deferred compensation				784			784
Stock option income tax benefits			8,677				8,677
Comprehensive income:							
Net income						60,089	60,089
Unrealized losses on short-term investments, net of income tax benefits of $496					(950)		(950)
Foreign currency translation adjustment					(1,088)		(1,088)
Comprehensive income							58,051
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 of income taxes of $111				251		251
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)
	(24)		(1,474)			(1,474)

Repurchase and retirement of restricted shares for employee taxes							
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

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and summary of significant accounting policies

Organization and basis of presentation

Gen-Probe Incorporated (Gen-Probe or the Company) is engaged in developing, manufacturing and marketing of rapid, accurate and cost effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and the screening of 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 25 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 in countries throughout the world. The Company is currently developing nucleic acid probe-based products that it hopes to introduce in the clinical diagnostic, blood screening and industrial microbiology testing markets, including products for the detection of human papillomavirus (HPV).

Certain prior year amounts have been reclassified to conform with the current year presentation. In the fourth quarter of 2007, the Company began reporting the amortization of premiums on investments, net of accretion of discounts, as an adjustment to reconcile net income to net cash provided by operating activities on the consolidated statement of cash flows. These amounts were previously reported as part of the proceeds from sales and maturities of short-term investments line under investing activities. This reclassification increased cash provided by operating activities for the years ended December 31, 2007, 2006 and 2005 by $4,576,000, $3,204,000 and $3,371,000, respectively.

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales and Service, Inc., Gen-Probe International, Inc., Gen-Probe UK Limited (GP UK Limited) and Molecular Light Technology Limited (MLT) and its subsidiaries. Prior to the second quarter of 2007, MLT and its subsidiaries were consolidated into the Company s financial statements one month in arrears. During the second quarter of 2007, as part of MLT s integration onto the Company s enterprise resource planning (ERP) system, the lag time between reporting periods was eliminated. The effect of this change was immaterial to the Company s financial statements. 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 collectibility 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, 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. 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 reported as a separate component of stockholders equity under the caption Accumulated other comprehensive income (loss).

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment and interest income.

Realized gains and losses, and declines in value judged to be other-than-temporary on short-term investments, are included in investment and interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in 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 11.

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.

Fair value of financial instruments

The carrying value of cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities approximates 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

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (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. The Company has no awards with market or performance conditions. The Company adopted the provisions of SFAS No. 123(R) using a modified prospective application. Accordingly, 2005 results were not revised for comparative purposes. Stock-based compensation expense recognized is based on the value of

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

share-based payment awards that are ultimately expected to vest, which coincides with the award holder s requisite service period. Also, certain of these costs are capitalized into inventory on the Company s balance sheet, and generally are recognized as an expense when the related products are sold. Estimated compensation expense for awards outstanding on January 1, 2006 is recognized over the remaining service period using the compensation cost calculated for pro forma disclosures under SFAS No. 123, Accounting for Stock-Based Compensation.

Upon adoption of SFAS No. 123(R), the Company elected to value its share-based payment awards using the Black-Scholes-Merton option-pricing model, which was previously used for its pro forma information required under SFAS No. 123. Prior to the adoption of SFAS No. 123(R), compensation cost was amortized over the vesting period using an accelerated graded method. In conjunction with the adoption of SFAS No. 123(R), the Company now amortizes all new grants as expense on a straight-line basis over the vesting period. See Note 2 for a complete discussion of the Company s stock-based compensation programs.

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.

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

	Years Ended December 31		
	2007	2006	2005
Net income	$ 86,140	$ 59,498	$ 60,089
Weighted average shares outstanding Basic	52,975	51,538	50,617
Effect of dilutive common stock options outstanding	1,547	1,563	1,828
Weighted average shares outstanding Diluted	54,522	53,101	52,445
Net income per share:			
Basic	$ 1.63	$ 1.15	$ 1.19
Diluted	$ 1.58	$ 1.12	$ 1.15

Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 1,556,134, 1,338,788 and 210,995 for the years ended December 31, 2007, 2006 and 2005, 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 its 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, its 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

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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 amounts it charges for its diagnostic assays. The Company has also implemented multi-year sales contracts that have an equipment factor set forth in them. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of an instrument, which ranges from three to five years; generally, three years for luminometers and DTS 400/800 instruments, and five years for TIGRIS and DTS 800/1600 instruments. 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 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.

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 first shipment of FDA-approved and labeled product following commercial approval, the Company classifies sales of these products as product sales in its financial statements.

The Company follows the provisions of Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF Issue No. 00-21), 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 related to the element. 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 balance sheet.

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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 (SFAS No. 2) 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.

Shipping and handling expenses

Shipping and handling expenses included in cost of product sales totaled approximately $5,607,000, $4,951,000, and $4,280,000 for the years ended December 31, 2007, 2006 and 2005, 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 include amounts related to materials, 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 on the consolidated balance sheet. All costs related to abandoned patent applications are recorded as general and administrative expenses.

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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	3-7
Furniture and fixtures	3

Depreciation expense was $26,592,000, $21,190,000 and $16,265,000 for the years ended December 31, 2007, 2006 and 2005, respectively. Amortization of leasehold 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 5 for further details of the Company s intangible assets and related amortization expense.

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 (SFAS No. 142).

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 2007 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.

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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.

Self-insurance reserves

The Company s consolidated balance sheets at December 31, 2007 and 2006 include approximately $1,965,000 and $1,698,000, 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 utilizing an actuarial method that is 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 the changes in claims experience, including changes in the number of incidents (frequency) and change in the ultimate cost per incident (severity).

Accumulated other comprehensive income (loss)

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. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income (loss), which includes certain changes in stockholders equity such as foreign currency translation of the Company s wholly owned subsidiary s financial statements and unrealized gains and losses on their 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Adoption of recent accounting pronouncements

In July 2006, the Financial Accounting Standards Board (FASB), issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes an interpretation of SFAS No. 109 (FIN No. 48), which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN No. 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. FIN No. 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted this statement effective January 1, 2007. In accordance with the transition guidance provided by FIN No. 48, the Company adjusted its 2007 opening retained earnings by the net impact of the derecognition of certain tax positions, which was $962,000. Further, the Company recorded an adjustment to increase the 2007 opening balance of net tax liabilities by $962,000.

Pending adoption of accounting pronouncements

SFAS No. 157

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors request 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 statements issued for fiscal years beginning after November 15, 2007. The Company does not anticipate the adoption of SFAS No. 157 will have a material effect on its consolidated financial position, results of operations or liquidity.

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). 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 is currently determining whether fair value accounting is appropriate for any of its eligible items and cannot estimate the impact, if any, that SFAS No. 159 will have on its consolidated financial position, results of operations or liquidity.

EITF 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). 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

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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. 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. EITF Issue No. 07-1 is effective for fiscal years beginning after December 15, 2008 for all collaborative arrangements existing as of that date, with retrospective application to all periods. The Company does not anticipate the adoption of EITF Issue No. 07-1 will have a material effect on its financial position, results of operations or liquidity.

EITF 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). EITF Issue No. 07-3 requires that nonrefundable 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 does not anticipate the adoption of EITF Issue No. 07-3 will have a material effect on its consolidated financial position, results of operations or liquidity.

SFAS No. 141(R)

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations (SFAS No. 141(R)). 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 for the Company 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). 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. 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 the Company had a consolidated subsidiary with a non-controlling interest. As of December 31, 2007, the Company does not have any consolidated subsidiaries in which there is a non-controlling interest.

2. Stock-based compensation

Share-based payment

On January 1, 2006, the Company adopted 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. The Company has no

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awards with market or performance conditions. The Company adopted the provisions of SFAS No. 123(R) using a modified prospective application. Accordingly, 2005 results were not 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. Certain of these costs are capitalized into inventory on the Company s balance sheet, and generally 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 purchased under the Company s stock option plan and Employee Stock Purchase Plan (ESPP):

	Stock Option Plans			ESPP		
	2007	2006	2005	2007	2006	2005
Risk-free interest rate	4.6%	4.8%	4.0%	5.0%	4.4%	3.0%
Volatility	36%	42%	49%	29%	40%	48%
Dividend yield						
Expected term (years)	4.2	4.5	5.2	0.5	0.5	0.5
Resulting average fair value	$ 21.44	$ 20.75	$ 21.02	$ 12.88	$ 12.76	$ 10.86

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.

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

Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of December 31, 2007
Options	1.6	$ 39,573
ESPP	0.2	72
Restricted Stock	1.6	10,512
Deferred Issuance Restricted Stock	1.4	2,122
		$ 52,279

At December 31, 2007, the Company had 282,896 unvested restricted stock and Deferred Issuance Restricted Stock Awards that had a weighted average grant date fair value of $53.97 per share. The fair value of the 67,540 restricted stock and Deferred Issuance Restricted Stock awards that vested during 2007 was approximately $3,060,000.

Impact of SFAS No. 123(R)

The following table summarizes the stock-based compensation expense for stock options and ESPP shares that the Company recorded in its statement of income in accordance with SFAS No. 123(R), excluding restricted stock (in thousands, except per share data):

	Years Ended December 31	
	2007	2006
Cost of product sales	$ 2,957	$ 2,264
Research and development	4,225	7,360
Marketing and sales	2,144	2,828
General and administrative	6,659	8,809
Reduction of operating income before income taxes	15,985	21,261
Income tax benefit	(5,948)	(7,636)
Reduction of net income	$ 10,037	$ 13,625
Reduction of net income per share:		
Basic	$ 0.19	$ 0.26

Diluted	$ 0.18	$ 0.26

Pro forma information for periods prior to adoption of SFAS No. 123(R)

Prior to adopting the provisions of SFAS No. 123(R), the Company used the intrinsic value method of recording its estimated compensation expense for employee stock options pursuant to Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), and provided the required pro forma disclosures of SFAS No. 123. Because the Company established the exercise price based on the fair market value of the Company s stock at the date of grant, the stock options had no intrinsic value upon grant, and therefore no estimated expense was recorded prior to adopting SFAS No. 123(R).

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For purposes of pro forma disclosures under SFAS No. 123, the estimated fair value of share-based payments are assumed to be amortized to expense over the vesting periods. The pro forma effects of recognizing estimated compensation expense under the fair value method on net income and net income per share for the year ended December 31, 2005 were as follows (in thousands, except per share data):

	December 31, 2005
Net income:	
As reported	$ 60,089
Stock-based employee compensation expense included in reported net income, net of related tax effects	470
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(15,309)
Pro forma net income	$ 45,250
Net income per share:	
As reported	
Basic	$ 1.19
Diluted	$ 1.15
Pro forma	
Basic	$ 0.89
Diluted	$ 0.86

3. Balance sheet information

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

Inventories

	December 31	
	2007	2006
Raw materials and supplies	$ 7,774	$ 9,479
Work in process	23,829	25,018
Finished goods	16,937	17,559
	$ 48,540	$ 52,056

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property, plant and equipment

	December 31	
	2007	2006
Land	$ 13,862	$ 13,862
Building	69,946	70,928
Machinery and equipment	139,871	128,572
Leasehold improvements	32,614	28,185
Furniture and fixtures	16,146	15,995
Construction in-progress	181	618
Property, plant and equipment (at cost)	272,620	258,160
Less accumulated depreciation and amortization	(143,127)	(123,546)
Property, plant and equipment (net)	$ 129,493	$ 134,614

4. Short-term investments

The following is a summary of short-term investments (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2007				
Municipal securities	$ 355,216	$ 2,448	$ (133)	$ 357,531
Foreign debt securities				
Total short-term investments	$ 355,216	$ 2,448	$ (133)	$ 357,531
December 31, 2006				
Municipal securities	$ 195,566	$ 30	$ (1,085)	$ 194,511
Foreign debt securities	7,497			7,497
Total short-term investments	$ 203,063	$ 30	$ (1,085)	$ 202,008

Gross realized gains from the sale of short-term investments were $0, $260,000 and $3,000 for the years ended December 31, 2007, 2006 and 2005, respectively. Gross realized losses from the sale of short-term investments were $274,000, $130,000 and $72,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2007, by contractual maturity, are as follows (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Maturities				
Within one year	$ 109,712	$ 196	$ (29)	$ 109,879
After one year through five years	245,504	2,252	(104)	247,652
Total short-term investments	$ 355,216	$ 2,448	$ (133)	$ 357,531

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table shows the gross unrealized losses and estimated fair values of 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, aggregated by investment category (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2007				
Municipal securities	$ 26,199	$ (52)	$ 29,439	$ (81)

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2006				
Municipal securities	$ 78,956	$ (257)	$ 90,804	$ (828)

The unrealized losses on the Company s investments in municipal securities were caused by market interest rate increases. 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 to be other-than-temporarily impaired at December 31, 2007 since the Company has the ability and intent to hold those investments until a recovery of fair value, which may be at maturity.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. 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 7 years at December 31, 2007). 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					
		2007			2006		
		Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible and other assets:							
Capitalized software	10	$ 25,142	$ 9,219	$ 15,923	$ 25,142	$ 6,705	$ 18,437
Goodwill	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	2,500		2,500
Investment in Qualigen, Inc.	N/A	6,993		6,993	6,993		6,993
Patents	8	17,304	16,286	1,018	16,689	15,353	1,336
Purchased intangible assets	20	33,636	33,002	634	33,636	32,666	970
License and manufacturing access fees	10	53,326	10,186	43,140	51,726	6,402	45,324
Other assets	N/A	3,911		3,911	2,293		2,293
		$ 117,670	$ 59,474	$ 58,196	$ 113,837	$ 54,421	$ 59,416

As of December 31, 2007, the Company had capitalized $15,923,000, net, in software costs associated with development of the TIGRIS instrument. In addition, the Company had an aggregate of $31,305,000 in TIGRIS-related items consisting of inventories, property, plant and equipment and prepaid expenses.

In April 2006, pursuant to the Company s November 2004 License and Preferred Stock Acquisition Agreement with Qualigen, Inc. and based upon the results of an 18-month technical evaluation study, the Company exercised its option to obtain an exclusive worldwide license to Qualigen technology to develop a novel NAT system based on Qualigen s FDA-approved FastPack® immunoassay system. If development is successful, the new system, known as a closed

unit-dose assay system, would use the Company s NAT technologies to detect microorganisms and genetic mutations at the point of sample collection. As a result of the option exercise, the Company paid Qualigen $6,993,000 for the purchase of an aggregate number of shares of Qualigen Series D Convertible Preferred Voting Stock and Series D-1 Convertible Preferred Non-Voting Stock convertible into approximately 19.5% of Qualigen s capital stock, on an as converted to common stock basis, as of the purchase date. Gen-Probe may also pay Qualigen up to $3,000,000 based on achievement of development milestones under the license agreement and agreed to pay Qualigen royalties on sales of any product developed by Gen-Probe under the agreement. The Company has recorded this equity investment as an intangible asset on a cost basis and will review the asset for impairment on an ongoing basis. At December 31, 2007, there were no indications of impairment.

In October 2005, the Company entered into a non-exclusive collaboration with Molecular Profiling Institute, Inc. (Molecular Profiling), a private company, to accelerate market development for the Company s pipeline of cancer diagnostics. Under the terms of the agreement, Molecular Profiling agreed to validate, commercialize and

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

undertake market development activities for up to four of the Company s products, starting with the Company s analyte specific reagents to detect PCA3, a genetic marker for the detection of prostate cancer. In addition, in October 2005, the Company paid Molecular Profiling $2,500,000 for the purchase of an aggregate number of shares of Molecular Profiling Series B Convertible Preferred Stock convertible into approximately 6.0% of Molecular Profiling s capital stock, on an as converted to common stock basis, as of the purchase date. The Company recorded its $2,500,000 investment on a cost basis. Subsequent to year end, in January 2008, the Company received cash for its shares in Molecular Profiling. See Note 15 for a discussion of this transaction.

In February 2005, the Company entered into a supply and purchase agreement with F. Hoffman-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc. (together referred to as Roche). Under this agreement, Roche agreed to manufacture and supply the Company DNA oligonucleotides for HPV for which the Company will pay transfer fees. The Company plans to use these DNA oligonucleotides in molecular diagnostic assays. Pursuant to the agreement, the Company paid Roche manufacturing access fees of $20,000,000, which were capitalized as an intangible asset and is being amortized over its economic life. The Company will also pay $10,000,000 within 10 days of the occurrence of certain future commercial events, but not later than December 1, 2008.

The Company had aggregate amortization expense of $7,567,000, $6,272,000 and $6,370,000 for the years ended December 31, 2007, 2006 and 2005, respectively, including $2,514,000 for software capitalization 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
2008	$	7,688
2009		7,536
2010		7,124
2011		7,085
2012		7,031
Thereafter		24,251
Total	$	60,715

6. 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, 2007, 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, 2007.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Income tax

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

	Years Ended December 31		
	2007	2006	2005
United States	$ 109,431	$ 91,297	$ 91,894
Rest of World	2,166	1,697	(200)
	$ 111,597	$ 92,994	$ 91,694

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

	Years Ended December 31		
	2007	2006	2005
Current:			
Federal	$ 31,243	$ 37,225	$ 35,890
Rest of World	541	300	(103)
State	1,826	1,999	684
	33,610	39,524	36,471
Deferred:			
Federal	(7,816)	(7,821)	(5,798)
Rest of World	(26)	(58)	40
State	(311)	1,851	892
	(8,153)	(6,028)	(4,866)
	$ 25,457	$ 33,496	$ 31,605

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31	
	2007	2006
Deferred tax assets:		
Research and other tax credit carry-forwards	$ 3,092	$ 3,366
Inventory reserves and capitalization	3,501	2,173
Deferred revenue	2,881	1,672
Deferred compensation	1,577	1,403
Stock compensation	12,061	8,316
Accrued vacation	2,121	1,994
Other accruals and reserves (net)	1,217	1,326
Total deferred tax assets	26,450	20,250
Valuation allowance		(301)
Total net deferred tax assets	26,450	19,949
Deferred tax liabilities:		
Other intangibles	(1,123)	(1,123)
Capitalized costs expensed for tax purposes	(6,901)	(7,699)
Depreciation	(924)	(1,816)
Unrealized gains on short-term investments	(810)	
Total deferred tax liabilities	(9,758)	(10,638)
Net deferred tax assets	$ 16,692	$ 9,311

The valuation allowance previously established against a capital loss carry-forward has been removed as the Company has determined it is more likely than not that these benefits will be realized as a result of anticipated capital gains to be realized in 2008. The valuation allowance also decreased during the year as foreign tax credits were realized as a result of the completed federal audit of the Company s tax returns through 2004.

At December 31, 2007, the Company also had California research and development credit carry-forwards of approximately $4,756,000, 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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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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					
	2007		2006		2005	
Expected income tax provision at federal statutory rate	$ 39,059	35%	$ 32,548	35%	$ 32,096	35%
State income tax provision, net of federal benefit	4,628	4%	3,850	4%	3,713	4%
Tax exempt interest income	(3,453)	(3)%	(1,981)	(2)%	(1,185)	(1)%
Research tax credits	(2,562)	(2)%	(2,004)	(2)%	(1,949)	(2)%
Settlements with tax authorities	(11,145)	(10)%		%		%
Other, net	(1,070)	(1)%	1,083	1%	(1,070)	(1)%
Actual income tax provision	$ 25,457	23%	$ 33,496	36%	$ 31,605	35%

Effective January 1, 2007, the Company adopted FIN No. 48. In accordance with the transition guidance provided by FIN No. 48, the Company increased its accrual for unrecognized tax benefits, principally related to research tax credits, by adjusting for the net impact of the change in guidance, which was $962,000. The adjustment was accounted for as a reduction in the beginning balance of retained earnings and an increase in the beginning balance of net tax liabilities. 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	$ 4,603

All of the unrecognized tax benefits, if recognized, would affect the Company s effective tax rate. The Company does not anticipate there will be a significant change in the unrecognized tax benefits within the next 12 months.

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 No. 48, $2,157,000 of interest and $0 of penalties were accrued as of January 1, 2007. As of December 31, 2007, the accrued interest balance was $397,000.

The Company s federal tax returns for the 2005 and 2006 tax years are currently under examination. Material filings subject to future examination are the Company s California tax returns for the 2005 and 2006 tax years.

Tax benefits of $14,606,000, $9,378,000 and $8,677,000 for the years ended December 31, 2007, 2006 and 2005, respectively, related to employee stock compensation programs were credited to stockholders equity.

8. Stockholders equity

Stock options

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	5,954	$ 29.53		
Granted	1,515	50.08		
Exercised	(913)	22.91		
Cancelled	(256)	40.45		

Outstanding at December 31, 2006	6,300		34.99			
Granted	1,182		59.11			
Exercised	(1,539)		29.32			
Cancelled	(425)		45.41			
Outstanding at December 31, 2007	5,518	$	40.86	7.3	$	122,683
Exercisable at December 31, 2007	3,082	$	31.91	6.1	$	96,072

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The Company defines in-the-money options at December 31, 2007 as options that had exercise prices that were lower than the $62.93 closing market price of its common stock at that date. The aggregate intrinsic value of options outstanding at December 31, 2007 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 5,365,008 shares that were in-the-money at that date. The total intrinsic value of options exercised during 2007 was $45,717,000, determined as of the exercise dates. The total fair value (using the Black-Scholes-Merton Model) of shares vested during 2007 was $24,286,000.

In addition, the Company had 80,000 shares of Deferred Issuance Restricted Stock Awards and 241,230 shares of restricted stock outstanding as of December 31, 2007 that have not been reflected in the table above.

A summary of the Company s unvested stock options at December 31, 2007, including the associated fair value of the awards using the Black-Scholes-Merton model, and changes during the year then ended is as follows (in thousands, except per share data and number of years):

	Number of Shares	Weighted Average Grant-Date Fair Value	Weighted Average Remaining Contractual Life (Years)
Unvested at December 31, 2006	2,959	$ 19.51	
Granted	1,182	21.44	
Vested	(1,284)	18.91	
Forfeited	(421)	19.63	
Unvested at December 31, 2007	2,436	$ 20.89	6.5

Additional information about stock options outstanding at December 31, 2007 with exercise prices less than or above $62.93 per share, the closing price as of December 31, 2007 (in thousands, except per share data):

	Exercisable		Unexercisable		Total	
As of December 31, 2007	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
In-the-money	3,079	$ 31.95	2,286	$ 51.29	5,365	$ 40.05
Out-of-the-money	3	67.44	150	66.73	153	66.74
Total options outstanding	3,082		2,436		5,518	

Shares of common stock available for future grants under all stock option plans were 1,447,485 at December 31, 2007.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31		
	2007	2006	2005
Exercise price equal to the fair value of common stock on the grant date:			
Weighted-average exercise price	$ 59.11	$ 50.08	$ 43.82
Weighted-average option fair value	$ 21.44	$ 20.54	$ 21.02
Exercise price greater than fair value of common stock on the grant date:			
Weighted-average exercise price	$	$	$
Weighted-average option fair value	$	$	$

Information under SFAS No. 123(R) for Periods Prior to 2006

	Options Outstanding					
	Shares Available for Grant	Number of Shares	Exercise Price per Share Range	Weighted Average	Restricted Stock Awards	Director Stock Purchases
	(In thousands)				(In thousands)	
December 31, 2004	1,915	6,004	$ 6.75 to 47.32	$ 25.03	40	
Granted	(1,363)	1,228	$ 36.23 to 50.91	43.82	132	3
Exercised		(890)	$ 6.75 to 47.32	17.65		(3)
Cancelled	388	(388)	$ 8.51 to 50.91	32.78		
December 31, 2005	940	5,954	$ 6.75 to 50.91	$ 29.53	172	

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, 2007, 2006 and 2005, employees purchased 74,337, 81,356 and 96,779 shares at an average price of $47.76, $42.85 and $30.87 per share, respectively. As of December 31, 2007, a total of 580,596 shares were available for future

issuance under the ESPP.

9. Commitments and contingencies

Lease commitments

The Company leases certain facilities under operating leases that expire at various dates through August 31, 2009. In February 2008, the Company completed the acquisition of the facility where it manufactures its blood screening products, which was previously leased. See Note 15 for a discussion of the purchase.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Future minimum payments under operating leases as of December 31, 2007 are as follows (in thousands):

2008	$ 103
2009	70
2010	
2011	
Total payments	$ 173

Rent expense was $1,022,000, $2,172,000 and $2,938,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

Purchase commitments

The Company is currently developing a new instrument platform, called the Panther instrument system, designed to bring the benefits of full automation and a broad molecular diagnostics menu to low to mid-volume customers. In July 2007, the Company authorized Stratec Biomedical Systems AG (Stratec), to commence its Phase 2 development activities pursuant to its Development Agreement for the Panther instrument system. Stratec is providing services for the design and development of the Panther Instrument System at a fixed price of $9,400,000, to be paid in installments due upon achievement of specified technical milestones. In addition, the Company will purchase prototype, validation, pre-production and production instruments, at specified fixed transfer prices, that will cost approximately $10,200,000 in the aggregate if it elects to purchase the number of each instrument type it currently expects to purchase. The Company will also purchase production tooling from Stratec at a cost of approximately $1,200,000.

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 $26,120,000 as of December 31, 2007. Of the $17,270,000 in TIGRIS instruments expected to be purchased, the Company anticipates that approximately $12,823,000 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. During 2007, 2006 and 2005, the Company recorded to cost of products sold $5,020,000, $3,598,000 and $3,334,000, 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.

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Bayer Corporation (now Siemens Healthcare Diagnostics, Inc.)

In June 2006, the Company entered into a Short Form Settlement Agreement with Bayer HealthCare LLC and Bayer Corp. (collectively, Bayer), to resolve patent litigation filed by the Company 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 the Company and Bayer were terminated pursuant to the Settlement Agreement.

Pursuant to the terms of the Settlement Agreement, the Company dismissed the patent litigation it filed against Bayer and granted Bayer immunity from suit for all current Bayer nucleic acid diagnostic products. The Company also agreed not to assert four specified patents against future Bayer products. Bayer granted the Company immunity from suit for the Company s current TIGRIS instrument and agreed not to assert certain specified Bayer patents against the Company s future instruments.

Pursuant to the Settlement Agreement, Bayer paid the Company an initial license fee of $5,000,000 in August 2006. Bayer also paid the Company $10,300,000 as a one-time royalty on January 31, 2007 and $16,400,000 as a one-time royalty on January 31, 2008. As a result of these royalty payments, Bayer s rights to the patents subject to the Settlement Agreement are fully paid-up and royalty free.

Pursuant to the Settlement Agreement, the Company has an option to extend the term of the license granted to the Company 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 the Company to elect to extend the license to future instrument systems (but not to the TIGRIS instrument). The Company is required to exercise the option prior to the expiration of the existing license in October 2010 and, if exercised, pay a $1,000,000 fee.

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 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. 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 has been set for October 2008.

On December 8, 2006, the Company filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a declaratory judgment that the supply and purchase agreement was valid and does not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit the Company to join the arbitration, the San Diego County Superior Court entered judgment dismissing the Company s complaint.

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.

10. 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 blood screening and certain areas of clinical

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

diagnostics. Under the terms of the collaboration agreement, Novartis or a third party will market and sell products that utilize Novartis intellectual property relating to 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.

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 WNV assay to the FDA in February 2005. For the years ended December 31, 2007, 2006 and 2005, the Company recognized $0, $9,205,000 and $18,369,000, respectively, in collaborative research revenue through its collaboration with Novartis from deliveries of WNV tests on a cost recovery basis. For the years ended December 31, 2007, 2006 and 2005, the Company recognized $355,000, $1,009,000 and $1,972,000, 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.

The Company is currently developing the Procleix Ultrio assay, a NAT assay to detect HIV-1, HCV and hepatitis B virus (HBV), in donated human blood. 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, 2007, 2006 and 2005, the Company received $5,525,000, $1,591,000 and $2,759,000, respectively, in reimbursements for expenses incurred related to the development of the Procleix Ultrio assay from Novartis.

From inception through December 31, 2007, the Company recognized a total of $828,787,000 in revenue under this collaboration agreement and had recorded $3,667,000 in deferred license revenues as of December 31, 2007.

bioMérieux Vitek, Inc.

Effective May 2, 1997, the Company entered into collaborative research agreements with bioMérieux Vitek, Inc. (bMx), which created a worldwide relationship between Gen-Probe and bMx. In August 2000, the Company entered into amended agreements with bMx that transitioned the relationship from a collaborative arrangement to

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, the Company entered into a termination agreement with bMx, which terminated one of the August 2000 license agreements. Pursuant to the termination agreement, bMx paid the Company an aggregate of approximately $1,600,000 to conclude certain outstanding royalty and other obligations under the terminated license agreement. Further, the Company paid $1,000,000 to bMx to gain access to bMx s intellectual property for detecting genetic mutations that predispose people to blood clotting disorders. In February 2006, bMx terminated the second of the two August 2000 license agreements. In December 2006, bMx paid the Company $350,000 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 the Company entered into the first termination agreement referenced above, the Company also entered into non-exclusive licensing agreements with bMx and its affiliates that provide bMx s affiliates options to access the Company s ribosomal RNA technologies for certain uses. The Company refers to these agreements as the Easy Q agreement and the GeneXpert agreement. Pursuant to the terms of these agreements, bMx s affiliates paid the Company an aggregate of $250,000 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 the Company s patented ribosomal RNA technologies. The first of these options was exercised by bMx s affiliates payment to the Company of $4,500,000 in January 2005. In December 2005, bMx s affiliates exercised a second option and paid the Company $2,100,000. The Company recognized an aggregate of $3,877,000 as license revenue in 2005 as a result of these payments. bMx s affiliates had an option to pay $1,000,000 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, the Company recognized a total of $2,973,000 as revenue in 2006 for amounts previously paid by bMx but deferred.

Under each license, the Company will receive royalties on the net sale of any products bMx and its affiliates develop using the Company s 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 bMx or its affiliates, the Company has the right to terminate these agreements, and the respective licenses granted to bMx s affiliates thereunder, upon 60 days prior written notice to bMx delivered within six months of the date of the change in control. The respective obligations of bMx s affiliates under the agreements is guaranteed by bMx SA, the parent company of the bMx affiliates that are parties to the agreements.

11. Significant customers and geographic information

During the years ended December 31, 2007, 2006 and 2005, 45%, 48% and 52%, respectively, of total revenues were from Novartis. No other customer accounted for more than 10% of revenues in any fiscal year. As of December 31, 2007 and 2006, the portions of trade accounts receivable related to Novartis were 36% and 20%, respectively.

During the years ended December 31, 2007, 2006 and 2005, 46%, 47% and 48%, respectively, of product sales were from the sale of commercially approved blood screening products. Other revenues related to the development of blood screening products prior to commercial approval are recorded in collaborative research revenue as disclosed in Note 10, Collaborative and license agreements. During the years ended December 31, 2007, 2006 and 2005, 54%, 53% and 52%, respectively, of product sales were from the sale of clinical diagnostic products and instruments.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31		
	2007	2006	2005
Total revenue:			
North America	$ 322,907	$ 273,606	$ 236,474
Rest of World	80,107	81,158	69,491
	$ 403,014	$ 354,764	$ 305,965

12. Employee benefit plan

Effective May 1, 1990, Gen-Probe established a Defined Contribution Plan covering substantially all employees of Gen-Probe beginning the month after they are hired. Employees may contribute up to 20% of their compensation per year (subject to a maximum limit imposed by federal tax law). Gen-Probe is obligated to make matching contributions equal to a maximum of 50% of the first 6% of compensation contributed by the employee. The contributions charged to operations related to Gen-Probe employees totaled $1,614,000, $1,636,000 and $1,384,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

13. Deferred compensation plan

In May 2005, the Company s Board of Directors approved the adoption of a Deferred Compensation Plan (the Plan), which became effective as of June 30, 2005. The Plan allows certain highly compensated management, key employees and directors of the Company to defer up to 80% of annual base salary or director fees and up to 100% of annual bonus compensation. Deferred amounts are credited with gains and losses based on the performance of deemed investment options selected by a committee appointed by the Board of Directors to administer the Plan. The Plan also allows for discretionary contributions to be made by the Company. Participants may receive distributions upon (i) a pre-set date or schedule that is elected during an appropriate election period, (ii) the occurrence of unforeseeable financial emergencies, (iii) termination of employment (including retirement), (iv) death, (v) disability, or (vi) a change in control of the Company, as defined in the Plan. Certain key participants must wait six months following termination of employment to receive distributions. The Plan is subject to Internal Revenue Code Section 409A.

The Company may terminate the Plan at any time with respect to participants providing services to the Company. Upon termination of the Plan, participants will be paid out in accordance with their prior distribution elections and otherwise in accordance with the Plan. Upon and for twelve (12) months following a change of control, the Company has the right to terminate the Plan and, notwithstanding any elections made by participants, to pay out all benefits in a lump sum, subject to the provisions of the Code. As of December 31, 2007, the Company had approximately $3,320,000 of accrued deferred compensation, of which $1,427,000 and $1,893,000 have been classified as current and long term liabilities, respectively, on the face of the consolidated balance sheet.

14. Quarterly information (unaudited)

The following tables set forth the quarterly results of operations for each quarter within the two-year period ended December 31, 2007. The information for each of these quarters is unaudited and has been prepared on the same basis as the Company s audited consolidated financial statements. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2007				
Total product sales	$ 87,152	$ 93,897	$ 97,402	$ 92,426
Total revenues	101,051	101,281	101,733	98,949
Cost of product sales	29,160	30,178	31,810	28,493
Gross profit	57,992	63,719	65,592	63,933
Total operating expenses	70,235	76,625	80,423	76,437
Net income	21,475	27,002	17,251	20,412
Net income per share:				
Basic	$ 0.41	$ 0.51	$ 0.32	$ 0.39
Diluted	$ 0.40	$ 0.50	$ 0.31	$ 0.37

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2006				
Total product sales	$ 78,528	$ 77,813	$ 83,470	$ 85,496
Total revenues	86,256	85,222	92,227	91,059
Cost of product sales	26,609	25,300	24,298	27,675
Gross profit	51,919	52,513	59,172	57,821
Total operating expenses	65,455	65,472	70,750	68,782
Net income	14,228	13,325	14,811	17,134
Net income per share:				
Basic	$ 0.28	$ 0.26	$ 0.29	$ 0.33
Diluted	$ 0.27	$ 0.25	$ 0.28	$ 0.32

15. Subsequent events

On February 1, 2008, the Company completed the purchase of the facility where it manufactures blood screening products. The Company had previously been leasing this facility, which consists of 93,646 square feet, located in San Diego, California, since November 1997. The purchase price was $15,700,000.

In January 2008, Caris Diagnostics completed the acquisition of Molecular Profiling Institute, Inc. At December 31, 2007, the Company held a $2,500,000 equity investment in Molecular Profiling. Pursuant to this sale transaction, the Company s equity interest was converted into approximately $4,400,000 of 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 will record the $1,600,000 gain associated with the initial $4,100,000 received in January 2008, and record the remaining gain if and when any funds are released to the Company from escrow.

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SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS
For The Three Years Ended December 31, 2007
(In thousands)

	Balance at Beginning of Period	Addition Charged to Cost and Expenses	Deductions[1]	Balance at End of Period
Allowance for doubtful accounts:				
Year Ended December 31, 2007:	$ 670	$ 130	$ (81)	$ 719
Year Ended December 31, 2006:	$ 790	$ 122	$ (242)	$ 670
Year Ended December 31, 2005:	$ 664	$ 207	$ (81)	$ 790
Inventory reserves:				
Year Ended December 31, 2007:	$ 5,802	$ 1,043	$ (184)	$ 6,661
Year Ended December 31, 2006:	$ 6,175	$ 5,151	$ (5,524)	$ 5,802
Year Ended December 31, 2005:	$ 6,579	$ 2,480	$ (2,884)	$ 6,175

(1) Represents amounts written off against the allowance or reserves, or credited to earnings.

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INDEX TO EXHIBITS

Exhibit Number	Description
2.1(3)	Separation and Distribution Agreement, dated and effective as of May 24, 2002, and amended and restated as of August 6, 2002, by and between Chugai Pharmaceutical Co., Ltd. and Gen-Probe Incorporated.
3.1(3)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(8)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(20)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(22)	Certificate of Elimination of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(3)	Specimen common stock certificate.
10.1(2)	Transition Services Agreement, dated April 4, 2002, by and between Chugai Pharma USA, LLC and Gen-Probe Incorporated.
10.2(4)	Form of Tax Sharing Agreement between Chugai Pharma USA, LLC and Gen-Probe Incorporated.
10.3(22)	The 2000 Equity Participation Plan of Gen-Probe Incorporated (as last amended on November 16, 2006).
10.4(22)	The 2000 Equity Participation Plan Form of Agreement and Grant Notice for Non-Employee Directors (as last amended on November 16, 2006).
10.5(22)	The 2002 New Hire Stock Option Plan (as last amended on November 16, 2006).
10.6(22)	The 2002 New Hire Stock Option Plan Form of Agreement and Grant Notice (as last amended on November 16, 2006).
10.7(22)	The 2003 Incentive Award Plan of Gen-Probe Incorporated (as last amended on February 8, 2007).
10.8(22)	The 2003 Incentive Award Plan Form of Agreements and Grant Notices (as last amended on February 8, 2007).
10.9(14)	The 2003 Incentive Award Plan Form of Restricted Stock Award Agreement and Grant Notice, as amended.
10.10	Intentionally omitted.
10.11(8)	Employee Stock Purchase Plan.
10.12(4)	Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).*
10.13(4)	Addendum dated June 11, 1998 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).*
10.14(4)	Amendment dated December 7, 1999 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.15(1)	Amendment No. 2 dated February 1, 2000 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.16(4)	Amendment No. 3 effective April 1, 2002 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).*
10.17(6)	Amendment No. 4 effective March 5, 2003 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.18(7)	Amendment No. 5 effective January 1, 2004 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.19(7)	Future Blood Screening Assay Ultrio Addendum effective January 1, 2001 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis

	Vaccines and Diagnostics, Inc.).*
10.20(7)	Future Blood Screening Assay West Nile Virus Addendum effective June 1, 2003 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).*

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Exhibit Number	Description
10.21(1)	Supplemental Agreement dated April 2, 2001 to the Agreement dated June 11, 1998 for Development, Distribution and Licensing of TMA Products between Gen-Probe Incorporated and Bayer.*
10.22	Intentionally omitted.
10.23	Intentionally omitted.
10.24(1)	Distribution Agreement entered into May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.25(4)	Distributorship Arrangements Agreement entered into May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.26(1)	Renewal Amendment entered into November 2, 1999 to the Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.
10.27(1)	First Amendment entered into August 4, 2000 to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.28(8)	2003 Amendment to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997, entered into May 2, 2003 by and between Gen-Probe Incorporated and bioMérieux, S.A.*
10.29(9)	Ribosomal Nucleic Acid License and Option Agreement (for Easy Q Instrument) dated September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux B.V.*
10.30(9)	Guarantee Agreement dated September 30, 2004 by bioMérieux SA, on behalf of its subsidiary bioMérieux, Inc. in favor of Gen-Probe Incorporated.
10.31(9)	Ribosomal Nucleic Acid License and Option Agreement (for GeneXpert Instrument) dated September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux, Inc.*
10.32(9)	Guarantee Agreement dated September 30, 2004, by bioMérieux SA, on behalf of its subsidiary bioMérieux b.v. in favor of Gen-Probe Incorporated.
10.33(9)	Side Letter dated October 1, 2004 by and between Gen-Probe Incorporated, bioMérieux B.V., and bioMérieux, Inc.*
10.34(9)	License Agreement entered into September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux B.V.*
10.35	Intentionally omitted.
10.36(4)	License Agreement effective as of July 1, 2001 between Gen-Probe Incorporated and Rebio Gen, Inc. (as successor-in-interest to Chugai Diagnostics Science Co., Ltd.).
10.37(4)	Distribution Agreement effective as of September 1, 1998 between Gen-Probe Incorporated and Rebio Gen, Inc. (as successor-in-interest to Chugai Diagnostics Science Co., Ltd.).
10.38(4)	First Amendment effective June 30, 2002 to September 1, 1998 Distribution Agreement between Gen-Probe Incorporated and Rebio Gen, Inc. (as successor-in-interest to Chugai Diagnostics Science Co., Ltd.).*
10.39(4)	Co-Exclusive Agreement effective as of April 23, 1997 between Gen-Probe Incorporated and The Board of Trustees of the Leland Stanford Junior University.*
10.40(1)	Amendment No. 1 effective April, 1998 to the License Agreement effective April 23, 1997 between Stanford University and Gen-Probe Incorporated.*
10.41(4)	Non-Assertion Agreement effective as of February 7, 1997 between Gen-Probe Incorporated and Organon Teknika B.V.*
10.42	Intentionally omitted.

10.43	Intentionally omitted.
10.44	Intentionally omitted.
10.45	Intentionally omitted.
10.46	Intentionally omitted.
10.47	Intentionally omitted.

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Exhibit Number	Description
10.48	Intentionally omitted.
10.49(4)	Non-exclusive License Agreement dated June 22, 1999 between Gen-Probe Incorporated and Vysis, Inc.*
10.50(9)	Settlement Agreement entered into September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc.*
10.51(9)	Amendment to Nonexclusive License Agreement under Vysis Collins Patents entered into September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc.*
10.52(4)	Amended and Restated License Agreement dated June 19, 2002 between Gen-Probe Incorporated and The Public Health Research Institute of The City of New York, Inc.*
10.53(4)	Development, License and Supply Agreement entered into as of October 16, 2000 between Gen-Probe Incorporated and KMC Systems, Inc.*
10.54(1)	First Amendment made as of September, 2001 to Agreement entered into as of October 16, 2000 between Gen-Probe Incorporated and KMC Systems, Inc.*
10.55	Intentionally omitted.
10.56	Intentionally omitted.
10.57(4)	Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.58(1)	First Amendment effective as of February 12, 2001 between Gen-Probe Incorporated and Roche Diagnostics GmbH, the successor-in-interest to Boehringer Mannheim GmbH, to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.59(10)	Second Amendment effective as of August 31, 2004 between Gen-Probe Incorporated and Roche Diagnostics, the successor-in-interest to Boehringer Mannheim GmbH, to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.60(7)	License, Development and Cooperation Agreement between Gen-Probe Incorporated and DiagnoCure Inc. effective as of November 19, 2003.*
10.61(7)	Target License Agreement between Tosoh Corporation and Gen-Probe Incorporated effective as of January 1, 2004.*
10.62(7)	TRC License Agreement between Tosoh Corporation and Gen-Probe Incorporated effective as of January 1, 2004.*
10.63(7)	TMA License Agreement between Tosoh Corporation and Gen-Probe Incorporated effective as of January 1, 2004.*
10.64(8)	Supply Agreement entered into January 1, 2002 by and between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.65(8)	Supply Agreement Amendment Number One entered into June 4, 2004 by and between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.66(10)	License Agreement between AdnaGen AG and Gen-Probe Incorporated effective as of December 30, 2004.*
10.67(10)	License Agreement between Corixa Corporation and Gen-Probe Incorporated effective as of December 31, 2004.*
10.68	Intentionally omitted.
10.69	Intentionally omitted.
10.70	Intentionally omitted.
10.71	Intentionally omitted.

10.72(3)	Form of Indemnification Agreement between Gen-Probe Incorporated and its Executive Officers and Directors.
10.73(21)	Employment Offer Letter dated February 7, 2007 between the Company and Carl W. Hull.
10.74(21)	Employment Agreement dated February 13, 2007 between the Company and Carl W. Hull.

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Exhibit Number	Description
10.75(9)	Deferred Issuance Restricted Stock Conversion Agreement, Deferred Issuance Award Agreement and Election Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated October 8, 2004.
10.76(22)	Form of Employment Agreement Executive Team.
10.77(22)	Form of Employment Agreement Vice Presidents.
10.78(5)	Gen-Probe Incorporated Change-In-Control Severance Compensation Plan for Employees.
10.79(11)	Modified Blood Screening Instrument eSAS 2 Addendum effective January 1, 2002 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).*
10.80(11)	Amendment No. 6 effective January 1, 2004 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporation and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).*
10.81(11)	Supply and Purchase Agreement between Gen-Probe Incorporated, F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc. effective February 15, 2005.*
10.82(11)	Amendment dated February 1, 2005 to Deferred Issuance Restricted Stock Conversion Agreement, Deferred Issuance Award Agreement and Election Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated October 8, 2004.
10.83(12)	Employment Offer Letter, dated July 15, 2005, between Gen-Probe Incorporated and Stephen J. Kondor.
10.84(13)	Gen-Probe Incorporated Deferred Compensation Plan effective as of June 30, 2005.
10.85(13)	Deferred Issuance Restricted Stock Award Grant Notice and Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated May 20, 2005.
10.86	Intentionally omitted.
10.87(15)	Letter Agreement between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.), dated June 11, 1998.*
10.88(16)	Amendment No. 8 effective February 8, 2006 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporation and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.89(16)	2006 Amendment entered into May 1, 2006 to the Renewed Distributorship Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux, S.A.
10.90	Amendment No. 7 effective May 20, 2005 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.91(20)	2007 Gen-Probe Employee Bonus Plan.
10.92(17)	2006 Gen-Probe Employee Bonus Plan.
10.93	Amended and Restated Employment Agreement effective March 1, 2007 by and between Gen-Probe Incorporated and Henry L. Nordhoff.
10.94(18)	Amendment No. 1 to License, Development and Cooperation Agreement effective May 24, 2006 by and between Gen-Probe Incorporated and DiagnoCure, Inc.*
10.95(18)	Amendment No. 9 effective July 1, 2006 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc.).
10.96(19)	Settlement Agreement dated August 1, 2006 by and among Gen-Probe Incorporated, Bayer HealthCare LLC and Bayer Corporation.**
10.97(23)	Form of First Amendment to Employment Agreement (for Executive Vice Presidents and Vice Presidents).
10.98(23)	Gen-Probe Incorporated 2007 Executive Bonus Plan.

10.99(23)	Agreement between Gen-Probe Incorporated and Larry T. Mimms.
10.100(24)	Development Agreement for Panther Instrument System, effective November 22, 2006, by and between the Company and STRATEC Biomedical Systems AG.**
10.101(24)	Supply Agreement for Panther Instrument System, effective November 22, 2006, by and between the Company and STRATEC Biomedical Systems AG.**

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Exhibit Number	Description
10.102(24)	Letter Agreement regarding Development Agreement for Panther Instrument System, dated July 17, 2007, by and between the Company and STRATEC Biomedical Systems AG.**
10.103(25)	Employment Offer Letter between the Company and Christina Yang.
10.104(26)	Retirement Agreement dated May 24, 2007 between the Company and Niall M. Conway.
10.105(27)	Employment Offer Letter effective October 30, 2007 between the Company and Jorgine Ellerbrock.
10.106	Third Amendment effective as of January 1, 2007 between Gen-Probe Incorporated and Roche Diagnostics, the successor-in-interest to Boehringer Mannheim GmbH, to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.**
21.1	List of subsidiaries of Gen-Probe Incorporated.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification dated February 22, 2008, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification dated February 22, 2008, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification dated February 22, 2008, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification dated February 22, 2008, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

Filed herewith.

Indicates management contract or compensatory plan, contract or arrangement.

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

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

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

(2) Incorporated by reference to Gen-Probe s Amendment No. 1 to Registration Statement on Form 10 filed with the SEC on July 29, 2002.

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

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

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

(6) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on May 9, 2003.

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

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

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

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

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

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

(13) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on August 4, 2005.

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

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

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

(17) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on July 18, 2006.

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

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

(20) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on February 14, 2007.

(21) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on February 14, 2007.

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

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

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

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

(26) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on May 24, 2007.

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