GEN PROBE INC
Form 10-K
February 23, 2007

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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, 2006

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 $.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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer þ Accelerated Filer o Non-Accelerated Filer o

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

As of June 30, 2006, 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 $2.4 billion, based on the closing price of the registrant s common stock on the Nasdaq Global Select Market on that date. Shares of common stock held by each officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded because these persons may be considered affiliates. The determination of affiliate status for purposes of this calculation is not necessarily a conclusive determination for other purposes.

As of February 16, 2007, 52,296,663 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.

GEN-PROBE INCORPORATED

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PART I

TRADEMARKS AND TRADE NAMES

ACCUPROBE®, APTIMA®, APTIMA COMBO 2®, DTS®, GASDIRECT®, GEN-PROBE®, LEADER®, PACE®, 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 Medical Solutions Diagnostics, Inc., as assignee of Bayer Corporation. 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 is not intended to, and 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, and we 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 24 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. 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 38 employees. Our blood screening products are marketed and distributed worldwide by Novartis. In addition, we have agreements with Siemens Medical Solutions Diagnostics, Inc. (as assignee of Bayer Corporation), bioMérieux, Inc. and Fujirebio, through its subsidiary Rebio Gen, Inc., to market some of our 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, food 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, Millipore Corporation, or Millipore, and 3M Company, or 3M, 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.

We have achieved a leading position in the industry because of our technologically advanced and reliable NAT assays and instruments, complemented in the clinical diagnostics market by the capabilities of our sales force and technical support group. Our investment in research and development has enabled us to develop a portfolio of proprietary and patented technologies that we combine to create NAT products to meet our customers changing needs for rapid, accurate and cost-effective assays. We also have designed and developed, often with outside vendors, a range of instruments for use with our assays.

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.

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Product Development

We have developed and commercialized what we believe to be the world s first fully automated, integrated, high-throughput, NAT instrument system, the TIGRIS instrument. The TIGRIS instrument can significantly reduce labor costs and contamination risks in high-volume diagnostic testing environments and it also enables large blood collection centers to individually test donors blood. In December 2003, we received marketing clearance from the FDA for sexually transmitted disease, or STD, testing on the TIGRIS instrument using our APTIMA Combo 2 assay that detects chlamydia and gonorrhea. 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 October 2006, the FDA granted marketing clearance to run our individual APTIMA assays for chlamydia and gonorrhea on the TIGRIS instrument.

We have developed and manufacture the only FDA-approved blood screening assay for the simultaneous detection of HIV-1 and HCV, the Procleix HIV-1/HCV assay, which is marketed by Novartis. We have also developed the Procleix Ultrio assay, in collaboration with Novartis, which adds a component for hepatitis B virus, or HBV, to the previously FDA-approved Procleix HIV-1/HCV assay. In January 2004, the Procleix Ultrio assay, running on our enhanced semi-automated instrument system, or eSAS, received approval to apply the CE mark, which permitted Novartis to launch the product in the European Economic Area. In October 2006, the FDA granted marketing approval for the Procleix Ultrio assay to run on eSAS. 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, and to detect the presence of HBV. However, the initial pivotal study for the Procleix Ultrio assay was not designed to, and did not, demonstrate yield, defined as HBV-infected blood donations that are negative based on serology tests for HBV surface antigen and core antibody. Based on discussions with the FDA, we and Novartis expect to initiate a post-marketing study to demonstrate HBV yield in order to gain a donor-screening claim. We expect this study to begin in early 2007.

In October 2005, the FDA notified us that it considers our TIGRIS instrument not substantially equivalent for blood screening to our already cleared eSAS. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening use with the Procleix Ultrio assay. In January 2007, we submitted a supplement to the approved Biologics License Application, or BLA, to allow the assay to be performed on the TIGRIS instrument. There can be no assurance that the TIGRIS instrument will receive FDA approval for use with the Procleix Ultrio assay.

In March 2006, we began shipment to Novartis of the FDA-approved and labeled Procleix WNV assay for use with eSAS. In April 2006, we submitted to the FDA a prior-approval supplement to our WNV assay BLA adding the TIGRIS instrument and we submitted an application for 510(k) clearance of the TIGRIS instrument for use with the WNV assay at the same time. In June 2006, we received questions from the FDA regarding our 510(k) application for the TIGRIS instrument. In August 2006, we responded to the FDA s questions presented in a complete review letter we received in late July 2006, which set forth questions regarding the prior-approval supplement to the BLA adding the TIGRIS instrument. Both the BLA supplement and the 510(k) application must be approved before licensed testing with the WNV assay can begin on the TIGRIS instrument. There can be no assurance that these approvals will be received.

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), 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 57% of the total chlamydia and gonorrhea tests sold in the United States in 2006. 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. In November 2006, we entered into a collaboration agreement with 3M to develop, manufacture and commercialize NAT products to enhance food safety and increase the efficiency of testing for food producers.

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 and Group B Streptococcus.

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

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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.

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.

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, 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. The Prostate Cancer Foundation estimates that in 2007, more than 218,000 men in the United States will be diagnosed with prostate cancer, and more than 27,000 men will die from the disease. We are also developing tests to detect human papillomavirus, or HPV, which has been linked to cervical cancer. According to the International Agency for the Research on Cancer (IARC), cancer of the cervix is the second most common cancer among women worldwide with more than 450,000 new cases, and 225,000 deaths, per year. IARC has shown that HPV infection precedes the development of cervical cancer in 99.7% of the cases.

Blood Screening. The field of blood screening has been one of the fastest growing areas for NAT assays. 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. The most serious threats to recipients of donated blood include HIV, HCV and HBV. There is also concern over the presence of other viruses in the donated

blood supply, such as WNV. 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 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

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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. IDT on our TIGRIS instrument was demonstrated as part of our Procleix WNV TIGRIS Investigational New Drug application, or IND.

Industry Growth Trends

Adoption of amplified screening technology. We believe that the market for 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 the introduction 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 and the herpes simplex virus. 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 each of 2004 through 2006, various blood collection centers used our technology and assays, under an investigational exemption, 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. We acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure in November 2003. Our license agreements with Corixa Corporation and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. could similarly permit an innovative application of our NAT technology to detect genetic markers for prostate cancer in

urine. 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 recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue. In January 2007, the U.S. 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. Receipt of funding under the award is subject to final administrative authorizations and timing of the award is uncertain.

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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 processes and testing for harmful contaminants in the environment, food, beverage 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, or PAT, 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, Millipore and 3M will facilitate our development of new products for, and access to, these new markets.

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 the areas of new analytes, such as genetic predisposition testing and pharmacogenomics, which involves the study of the relationship between nucleic acid variations and an individual s response to a particular drug.

We expect that diagnostic 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.

In addition to testing in the environment and for harmful contaminants in the biopharmaceutical, food and beverage manufacturing processes, emerging non-clinical markets for NAT include personal care products manufacturing 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.

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. Initial real-time products have been introduced by several companies. For example, Abbott Laboratories has been approved to apply the CE mark to a new 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. We expect to launch our first product under the Millipore collaboration in 2007.

Our Competitive Strengths

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

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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, which we estimate is currently utilized to screen over 80% of the United States donated blood supply for HIV-1 and HCV. In December 2005, the FDA approved our WNV assay for use on eSAS to screen donated human blood for WNV. 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) instruments. As of December 31, 2006, we had more than 430 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

We pioneered the development of the NAT market with our introduction of the first FDA-approved probe-based assay in 1985. As of December 31, 2006, our world-class research and development group consisted of 228 full-time employees, 96 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 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. Our current initiatives to expand our position in clinical diagnostics and blood screening, while applying our core NAT technologies to cancer detection and industrial testing, are consistent with our philosophy of designing innovative products to meet the existing needs of our customers as well as the emerging needs of new markets.

Brand Recognition

We believe that we benefit from significant brand name recognition and customer loyalty among laboratories, blood collection agencies and physicians in the market for NAT assays. We believe our history of technological innovation, quality manufacturing, comprehensive sales capabilities and commitment to customer support has resulted in customer satisfaction and retention. We estimate that greater than 90% of our STD product sales during 2006 were to repeat customers. We believe that our brand name also facilitates market acceptance of our new

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products, providing us with opportunities for growth. Based on information we receive from Novartis, we believe that since 1998 we have 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, 2006, our direct sales force consisted of 38 employees and a 43 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 20 years of overall sales experience, with an average of approximately nine 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 127 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. Our WNV assay, which received FDA marketing approval in December 2005 for screening donated human blood on eSAS, 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 developed analyte specific reagents, or ASRs, for the detection of PCA3, a genetic marker for prostate cancer, and we CE marked our PCA3 assay, allowing it to be marketed in the European Economic Area. 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. Our license and collaboration agreement with DiagnoCure Inc. and our license agreements with Corixa Corporation and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. could represent an innovative application of our NAT technology to detect genetic markers for prostate cancer in urine.

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We have also entered into three collaborations in the industrial testing market since July 2005. 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 food testing, respectively.

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. For example, we have developed and received FDA approval for testing chlamydia and gonorrhea on the TIGRIS instrument. The TIGRIS instrument should significantly reduce the time, labor costs, risk of contamination and complexity associated with performing NAT assays. We believe that the increased utility of this platform will lead to significant advances in both the NAT clinical diagnostics and blood screening markets. 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 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 Core Clinical Diagnostics and Blood Screening Businesses with New Products

We intend to continue to broaden our product platform through the introduction of new products to serve the clinical diagnostics and blood screening markets. We have a successful history of product development and in 2006 had nine FDA product approvals or clearances and thirteen product launches.

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 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 addition, 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 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 recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue.

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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 food 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;
- 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 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 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.

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

Our patented TMA technology is designed to overcome problems faced by other target amplification methods such as PCR. TMA is a transcription-based amplification system that uses two different enzymes to drive the process. The first enzyme is a reverse transcriptase that creates a double-stranded DNA copy from an RNA or DNA template. The second enzyme, an RNA polymerase, makes thousands of copies of the complementary RNA sequence, known as the RNA amplicon, from the double-stranded DNA template. Each RNA amplicon serves as a new target for the reverse transcriptase and the process repeats automatically, resulting in an exponential amplification of the original target that can produce over a billion copies of amplicon in less than 30 minutes.

TMA offers the following benefits:

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

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

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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. 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. We expect that our first products to utilize this format will be in the industrial testing market.

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. 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. We expect to introduce industrial testing products in the future.

Clinical Diagnostic Products.

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

Clinical Diagnostic Products for the Detection of Non-Viral Microorganisms. We have developed FDA-approved amplified and non-amplified NAT assays that detect non-viral 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

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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	
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* in swab specimens and urine samples from symptomatic and asymptomatic males and females	May 2001	Gen-Probe North America Europe Rebio Gen Japan

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Product Line	Principal Technologies	Target Microorganism	FDA Clearance/Approval	Commercial Distribution
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 U.S.
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 Group B Streptococcus, or GBS, from broth culture. The assay demonstrates near 100% sensitivity and specificity when testing broth samples after 24 hours of incubation. Our products address the market need for a more rapid, direct test procedure for GBS that can be used to effectively screen women during pregnancy and to provide prompt results when testing is performed just before delivery.

Group A Streptococcus Direct. The Group A Streptococcus Direct Test, or GASDirect assay, is a rapid NAT assay for the direct detection of *Streptococcus pyogenes* in one hour from a throat swab. Sensitivity and specificity are equivalent to culture methods taking 72 hours to complete and are higher than the rapid membrane antigen tests often used in physician offices. The test provides fast and accurate results, eliminates subjective interpretation by the laboratory technician, and aids physicians in making more informed treatment decisions. The product s ease of use enables efficient batch testing. An automatic pipetting option offers greater workflow economies and laboratory productivity.

PACE Product Family. Our PACE 2C was the first advanced NAT product to offer the convenience of testing for both chlamydia infections and gonorrhea from a single patient specimen. This feature eliminates the need to collect separate specimens and the need to transport the specimens under different conditions. The PACE 2C continues to meet the needs of clinical laboratories that prefer a cost-effective, non-amplified NAT assay for routine screening for chlamydia infections and gonorrhea. Other products in the PACE 2 product line include individual tests to separately detect and confirm both chlamydia infections and gonorrhea. The PACE product family also includes the PACE Specimen Collection kits for endocervical and urethral swab specimens. Sales of our PACE family of assays have declined in recent years due to two factors. First, our total revenues are increasing primarily due to growth in our blood-screening segment, which lowers the overall contribution of the clinical diagnostic revenues as a percentage of total revenues. Second, 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.

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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 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.

In March 2006, in response to FDA comments, we withdrew use of TriPath s liquid Pap transport media from the APTIMA *Chlamydia trachomatis* assay 510(k) application. We are deferring further FDA applications concerning use of our assays with the TriPath media.

Other APTIMA Products APTIMA CT, APTIMA GC and APTIMA Trichomoniasis 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 also have developed ASRs to detect the parasite *Trichomonas vaginalis* that causes the sexually transmitted disease trichomoniasis. 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. ASRs comprise a category of individual reagents utilized by clinical laboratories to develop and validate their own diagnostic tests, often referred to as home-brew tests. ASRs allow diagnostic companies to deliver reagents to the market rapidly, as most ASRs are exempt from FDA pre-market review.

Clinical Diagnostic Products for the Detection of Viral Microorganisms. In 1996, we were selected by the National Heart, Lung and Blood Institute of the National Institutes of Health, or NIH, to develop reagents and instrumentation for the blood donor screening market using our core technologies. Our work under the NIH contract also launched us into development of products for detection of viral microorganisms in the clinical diagnostic market. 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.

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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 U.S.
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. In collaboration with Bayer Corporation (now Siemens Medical Solutions Diagnostics, Inc.), we completed clinical trials in the United States for this assay in February 2002, and in November 2002, we received pre-market approval from the FDA. Siemens currently distributes this assay under the trademark VERSANT in the United States and other 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, an ASR to quantitatively determine the amount of HCV present in a sample. This ASR currently is provided by Siemens to Quest Diagnostics Incorporated, a leading national diagnostics company.

Clinical Diagnostic Products for the Detection of Markers for Cancer

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 95 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 of 2003. During the second quarter of 2006, two clinical laboratory customers in the United States completed validation of TMA

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assays for PCA3 and PSA, or prostate specific antigen, using our ASRs and general purpose reagents and began offering these tests to physicians and reporting patient results, employing a PCA3 to PSA ratio.

We are evaluating the possibility of combining tests for additional prostate cancer markers with a test for PCA3 in an assay or series of assays for the early detection of prostate cancer. In December 2004, we entered into a license agreement with Corixa 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 agreement with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. for access to additional markers that we believe could 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 recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue.

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 Dual Assay	Target Capture, Transcription-Mediated Amplification of viral RNAs, detection by plasma, organs and Kinetic Assay	WNV in donated blood, plasma, organs and tissues	December 2005	Novartis U.S.
Procleix Ultrio DualAssay	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. The Procleix HIV-1/HCV assay supplied under the IND was delivered on a cost recovery basis.

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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 by December 7, 2003 or before further distribution after that date. Products already in the EU supply chain on that date were permitted to remain in distribution for two additional years. We received CE mark approval for our initial Procleix HIV-1/HCV blood screening assay in February 2003, for the Procleix Ultrio assay in January 2004, and for the TIGRIS instrument, used in conjunction with the Procleix Ultrio assay, in December 2004.

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 will 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, the FDA granted marketing approval for use of the Procleix Ultrio assay on eSAS. 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, and to detect the presence of HBV. However, the initial pivotal study for the Procleix Ultrio assay was not designed to, and did not, demonstrate yield, defined as HBV-infected blood donations that are negative based on serology tests for HBV surface antigen and core antibody. Based on discussions with the FDA, we and Novartis will initiate a post-marketing study to demonstrate HBV yield in order to gain a donor-screening claim. We expect this study to begin in early 2007.

In October 2005, the FDA notified us that it considers our TIGRIS instrument not substantially equivalent for blood screening to our already cleared eSAS. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening use with the Procleix Ultrio assay. In January 2007, we submitted a supplement to the approved BLA to allow the assay to be performed on the TIGRIS instrument. There can be no assurance that the TIGRIS instrument will receive FDA approval for use with the Procleix Ultrio assay.

In June 2003, we announced clinical testing had commenced for WNV with our Procleix WNV assay by United States blood collection centers under an IND. We filed a BLA for the WNV assay with the FDA in January 2005. The development of the WNV assay was partially funded by the National Heart, Lung and Blood Institute of the NIH. On December 1, 2005, the FDA granted marketing approval for our 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 2006, we began shipment to Novartis of the FDA-approved and labeled Procleix WNV assay for use with eSAS. In April 2006, we submitted to the FDA a prior-approval supplement to our WNV assay BLA adding the TIGRIS instrument and we submitted an application for 510(k) clearance of the TIGRIS instrument for use with the WNV assay at the same time. In June 2006, we received questions from the FDA regarding our 510(k) application for the TIGRIS instrument. In August 2006, we responded to the FDA s questions presented in a complete review letter we received in late July 2006, which set forth questions regarding the prior-approval supplement to the BLA adding the TIGRIS instrument. Both the BLA supplement and the 510(k) application must be approved before

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licensed testing with the WNV assay can begin on the TIGRIS instrument. There can be no assurance that these approvals will be received.

Products for Emerging Diagnostic and Industrial Testing Applications

In addition to our license agreement with DiagnoCure for PCA3, we have licensed multiple potential markers for genitourinary and other cancers from Corixa, including a gene called AMACR that we believe is a promising marker for a molecular-based prostate cancer diagnostic test. We have also licensed innovative cell capture technology from AdnaGen that may allow for improved isolation of prostate cancer cells. In December 2005, we entered into a license agreement with the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. for access to additional markers that we believe could help us to further increase the accuracy of our tests for prostate cancer. In May 2006, we entered into a license agreement with the University of Michigan for exclusive worldwide rights to develop diagnostic tests for recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue.

In the industrial market, 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. In November 2006, we entered into a collaboration agreement with 3M to develop, manufacture and commercialize NAT products to enhance food safety and increase the efficiency of testing for food producers.

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.

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.

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The DTS 400 instruments are fully-integrated modular instruments that include a magnetic particle separation and washing system (target capture system), temperature controlled incubators, a luminometer, software, on board bar code readers and computers. The DTS 800 and 1600 instruments add the additional capabilities of an automated pipetting station, and the DTS 1600 instrument can process up to 800 specimens per day, resulting in 1,600 chlamydia and gonorrhea assay results per day for the APTIMA Combo 2 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 approximately 13 hours. In addition, two TIGRIS instruments can be operated under the supervision of a single lab technician.

The TIGRIS instrument is expected to reduce the time, labor costs, risk of contamination and complexity associated with performing NAT assays and blood screening. As demonstrated by the clinical testing of the Procleix WNV TIGRIS assay under an IND, the throughput of the TIGRIS instrument is sufficient to allow high volume testing of individual blood donations, rather than pooled donor samples. In addition, we intend to develop additional NAT assays that can be performed on the TIGRIS instrument. The TIGRIS instrument is being utilized in numerous clinical diagnostic laboratories and blood banks.

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 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, 2006, our direct sales force consisted of a staff of 38 sales employees. We also support our sales efforts through a staff of 43 field technical employees. Our sales representatives have an average of approximately 20 years of overall sales experience, with an average of approximately nine 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 generally do not focus on physicians. 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

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presenting multiple NAT technology and instrumentation options. Sales representatives are trained to find new product opportunities, offer diagnostic solutions to address unmet customer needs, and provide comprehensive after-sale product support. In addition, our field technical support group provides training and ongoing technical support for all of our NAT products.

Distributors

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

The viral diagnostic products we manufacture under our collaboration agreement with Siemens and the blood screening products we manufacture under our collaboration agreement with Novartis are marketed and distributed by those companies.

Customers

The primary customers for our clinical diagnostic products include large reference laboratories, public health institutions and hospitals. Our blood screening collaboration with Novartis accounted for 48% of our total revenues in 2006 and 52% of our total revenues in 2005. 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 2006. In addition, Quest Diagnostics, Laboratory Corporation of America Holdings and various state and city public health agencies accounted for an aggregate of 20% of our total revenues in each of 2006 and 2005. 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 Medical Solutions Diagnostics, Inc.). 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 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 the initial Procleix HIV-1/HCV assay through 2003 ranged from 43% to 47.5% after deduction of appropriate expenses. Effective January 1, 2004, we amended the collaboration agreement for assays that include a test for HCV to fix our share at 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. The amendment also eliminated the possibility of Novartis 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, 2006, 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

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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.

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 is more likely in 2008 than in 2007. There can be no assurance that the Procleix Ultrio assay will receive full regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the Procleix Ultrio assay.

From inception through December 31, 2006, we recognized a total of $646.9 million in revenue under this collaboration agreement and had recorded $4.3 million in deferred license revenues as of December 31, 2006.

Agreement with Siemens Medical Solutions 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 Medical Solutions Diagnostics, Inc. Pursuant to the collaboration, we and Siemens are manufacturing and marketing quantitative ASRs and qualitative assays for HCV. 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 the quantitative ASRs and qualitative assays for HCV.

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, 2006, we recognized a total of $18.7 million in revenue under our collaboration agreement with Siemens, including $6.7 million in revenue during 2006.

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.

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Pursuant to the Settlement Agreement, Bayer paid us an initial license fee of $5.0 million in August 2006. Additionally, Bayer agreed to pay us approximately $10.3 million as a one-time royalty if Bayer sells any product subject to our patents covered by the Settlement Agreement on or after January 1, 2007, and Bayer also agreed to pay us approximately $16.4 million as a one-time royalty if Bayer sells any product subject to our patents on or after January 1, 2008. Subject to these two royalty payments, Bayer s rights to the related patents will be fully paid-up and royalty free. On January 8, 2007, Siemens notified Bayer and us in writing that it is making and selling products subject to the license we granted and that Siemens believed the 2007 royalty of $10.3 million was due from Bayer. We received Bayer s payment on January 31, 2007.

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.

Distribution Agreement with Rebio Gen

In September 1998, we entered into a distribution agreement with Chugai Diagnostics Science Co., Ltd., a subsidiary of our parent corporation at that time, for the distribution of our non-viral diagnostic products in Japan. During 2002, Chugai Pharmaceutical sold Chugai Diagnostics Science Co., Ltd. to Fujirebio Inc., a Japanese life sciences company, which re-named the company Rebio Gen, Inc. Fujirebio Inc. is now a subsidiary of Macara Holdings. From inception through December 31, 2006, we recognized $24.8 million in sales revenue under this distribution agreement, including $3.4 million in sales revenue during 2006. The distribution agreement with Rebio Gen, as amended, currently expires by its terms on December 31, 2010. Prior to expiration, this agreement may be terminated by either party upon a material breach of this agreement that is not cured following 60 days written notice, unless the material breach relates to an obligation to make payments under the agreement, in which case a 30 day cure period applies. This agreement may also be terminated if a party becomes insolvent or declares bankruptcy, ceases to be actively engaged in business, or engages in or is charged with unethical or illegal behavior that jeopardizes the reputation and goodwill of either party.

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. 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 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 the supply and purchase agreement is null and void. We are not named as a party to Digene s arbitration and Digene has declined our request to join the arbitration.

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 seeks a declaratory judgment that the supply and purchase agreement is valid and does not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene.

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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.

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 ten 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 ten year period specified above. In addition, either party may terminate the agreement upon a breach of a material provision of the agreement by the other party that is not cured following 90 days written notice and in certain other limited circumstances.

Collaboration Agreement with Millipore

In August 2005, we entered into a collaboration agreement with Millipore to develop, manufacture and commercialize NAT products for rapid microbiological and viral monitoring for Millipore s exclusive use or sale in process monitoring in the biotechnology and pharmaceutical manufacturing industries. Under the terms of the agreement, we will be primarily responsible for assay development and manufacturing, while Millipore will manage worldwide commercialization of any products resulting from the collaboration. The agreement terminates upon the expiration of any two-year period during which there has been no development work conducted under the agreement or no first commercial sale of a product developed under the agreement. In addition, either party may terminate the agreement upon a material breach of the agreement by the other party that is not cured following 120 days written notice and in certain other limited circumstances. We expect to launch our first assay under the collaboration in 2007.

Agreements with Molecular Profiling Institute, Inc.

In October 2005, we entered into agreements with Molecular Profiling Institute, Inc. 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, a genetic marker for the detection of prostate cancer. 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.

Exclusive Development and Supply Agreement with 3M

In November 2006, we entered into an exclusive development and supply agreement with 3M to develop, manufacture and market innovative nucleic acid tests to enhance food safety and increase the efficiency of testing for food producers. Under the terms of the agreement, we will be primarily responsible for assay development and manufacturing, while 3M will manage worldwide commercialization of any products resulting from the

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collaboration. The agreement expires in November 2016. The agreement may be earlier terminated by 3M without cause upon proper notice and the payment of certain wind-down costs. We may terminate the agreement in certain circumstances if there has been no development work conducted 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 proper notice and in certain other limited circumstances.

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 Vitek, Inc., which created a worldwide relationship between bioMérieux and us.

In August 2000, we entered into amended agreements with bioMérieux, Inc. 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 options to access our ribosomal RNA 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 bioMerieux 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 any 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, 2006, we recognized a total of $3.3 million in revenue under this agreement, including $0.2 million in revenue during 2006. 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, 2006, we recognized a total of $5.3 million in revenue under this agreement, including $1.0 million in revenue during 2006. 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 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, 2006, we incurred a total of $6.3 million in expenses under this agreement, including $2.0 million in expenses during 2006. 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.

License from University of Wales College of Medicine. Our wholly-owned subsidiary, Molecular Light Technology Limited and its subsidiaries, collectively referred to as MLT, have exclusive rights, with rights to sublicense, under a license from the University of Wales College of Medicine, or UWCM, to patents covering AE

chemiluminescence technology. In 1986, prior to our acquisition of MLT, we entered into an agreement with MLT and UWCM pursuant to which we obtained an exclusive sublicense to the technology for use in NAT assays. This technology is an important component of our products and is used to reveal when a probe has bound to its target sequence. We will own all improvements to the chemiluminescence technology that we develop. 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 August 2007. Subsequent to our acquisition of a majority ownership of MLT in August 2003, through December 31, 2006, we paid royalties to UWCM totaling $5.7 million, including $1.0 million in 2006. The agreement with UWCM may also be terminated by a party upon breach of the agreement that is not cured following a specified notice provision.

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

In September 2004, following litigation between the parties concerning the scope, validity and enforceability of the licensed patents, we entered into a settlement agreement and an amendment to the non-exclusive license agreement. Under the settlement agreement, we agreed to terminate the litigation and pay Abbott an aggregate of $22.5 million. This aggregate amount included $20.5 million for a fully paid up license to eliminate all of our future royalty obligations under the license, and $2.0 million for a fully paid-up, royalty-free license in additional fields under the licensed patents. The paid-up license now covers current and future products in the field of infectious diseases and all other fields. Novartis reimbursed us $5.5 million of the $20.5 million allocated to the cost of the fully paid-up license for the current field, commensurate with its obligation to reimburse us for a portion of the royalties due on the sale of blood screening products.

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, 2006, we incurred a total of $2.1 million in license fees and $0.1 million in milestone payments under this agreement. We anticipate that we will pay up to an additional $0.4 million in milestone payments over the remaining term of the agreement. This 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. This 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

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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 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 are currently evaluating the possibility of combining tests for additional prostate cancer markers with a test for PCA3, in an assay or series of assays for the early detection of prostate cancer.

Exclusive Option Agreement with Qualigen, Inc. In November 2004, we entered into an agreement with Qualigen, Inc. under which we have 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.

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 to obtain exclusive licenses to use AdnaGen s technology in molecular diagnostic tests for kidney, ovarian and cervical cancers. In June 2006, we agreed to pay AdnaGen $0.2 million to extend this option period for an additional 12 months. If we exercise any of these options, we will pay AdnaGen $0.3 million for the exclusive license to each additional cancer product, as well as royalties on net sales of any of these additional cancer products using AdnaGen s technology. In addition, 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 Corporation 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

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milestone payments totaling an additional $2.0 million on a product-by-product basis based on the occurrence of certain, regulatory and/or commercial events. We also agreed to pay Corixa additional milestone payments and royalties on net sales of any products developed by us using Corixa s technology. The agreement will expire on the expiration of our obligation to pay royalties to Corixa under the agreement, which obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed patent rights. We may terminate the agreement in our sole discretion upon 30 days prior written notice to Corixa, provided we have made any outstanding payments due under the agreement. Either party may terminate the agreement for cause by written notice to the other party of an uncured material breach by the other party or if the other party is unable to pay its debts or enters into compulsory or voluntary liquidation.

License Agreement with University of Michigan. In April 2006, we entered into a license agreement with the University of Michigan for exclusive worldwide rights to develop and commercialize diagnostic tests for recently discovered genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue. In May 2006, pursuant to the terms of this agreement, we paid a license fee of $0.5 million to the University. We also agreed to pay royalties on eventual product sales, as well as development milestones. In addition, we will fund 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, 2006, we owned more than 430 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. 110 of our current United States utility patents issued from applications filed prior to June 8, 1995. 104 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 October 16, 2023. 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

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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 F. Hoffmann-La Roche Ltd. and its subsidiary Roche Molecular Systems, Inc., or, collectively, Roche, Abbott Laboratories, through its subsidiary Abbott Molecular Inc. or, collectively, Abbott, Becton Dickinson and Company, Siemens Medical Solutions Diagnostics, Inc. and bioMérieux S.A. 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. We believe the primary competitive factors in the NAT market are sensitivity, specificity, ease of use, automation, cost, proprietary position, regulatory approvals and compliance and, for clinical diagnostic tests, availability of appropriate reimbursement.

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 which 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. Abbott recently entered into a definitive agreement to sell its diagnostics division, which markets these products, to General Electric. 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

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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, 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. To the extent that Novartis grants additional licenses in blood screening or Siemens grants additional licenses in clinical diagnostics, further competition will be created for sales of HCV and HIV assays and these licenses could affect the prices that can be charged for our products.

Government Regulation

Our clinical diagnostic products generally are classified in the United States as devices and are regulated by the FDA s Center for Devices and Radiological Health. Our blood screening products generally are classified in the United States as biologics and are regulated by the FDA s Center for Biologics Evaluation and Research.

For us to market our clinical diagnostic product kits as medical devices in the United States, we generally must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FFDCA. If we modify our products that already have received FDA clearance, the FDA may require us to submit a separate 510(k), a special 510(k) or a premarket approval application, or PMA, for the modified product before we are permitted to market it in the United States. In addition, if we develop products in the future that are not considered to be substantially equivalent to a legally marketed device, we will be required to obtain FDA approval by submitting a PMA.

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

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

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- the FDA s general prohibition against promoting products for unapproved or off-label uses, and

- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur.

Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, suspension of export certificates and criminal prosecution.

Our blood screening products also are subject to extensive pre- and post-market regulation as biologics by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of the products under the FFDCA and the Public Health Services Act, and by comparable agencies in most foreign countries. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of preclinical testing,

- submission of an IND, which must become effective before clinical trials may begin, and

- performance of adequate and well controlled human clinical trials to establish the safety and effectiveness of the proposed biologic s intended use.

The FDA requires approval of a BLA before a licensed biologic may be legally marketed in the United States. Product approvals may be withdrawn or suspended if compliance with regulatory standards is not maintained or if problems occur following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have exclusive rights to exploit them.

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

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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.

Outside the United States, our ability to market our products is contingent upon maintaining our International Standards Organization (ISO) certification, and in some cases receiving specific marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. Our EU product registrations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

We are also subject to various state and local laws and regulations in the United States relating to laboratory practices and the protection of the environment. In each of these areas, as above, regulatory agencies have broad regulatory and enforcement powers, including the ability to levy fines and civil and criminal penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us. In addition, in the course of our business, we handle, store and dispose of chemicals. The environmental laws and regulations applicable to our operations include provisions that regulate the discharge of materials in the environment. Usually these environmental laws and regulations impose strict liability, rendering a person liable without regard to negligence or fault on the part of, or conditions caused by, others. We have not been required to expend material amounts in connection with our efforts to comply with environmental requirements. Because the requirements imposed by these laws and regulations frequently change, 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 Rancho Bernardo manufacturing facility in San Diego 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 demand for these blood screening assays. We also have manufacturing capability at MLT s facility in Cardiff, United Kingdom and expect that some space at our newly constructed 292,000 square-foot building adjacent to our San Diego headquarters will be utilized for manufacturing. 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 which 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

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suppliers to assure continuity of supply while maintaining high quality and reliability. Although we generally consider and identify alternative suppliers, we do not typically pursue alternative sources due to the strength of our existing supplier relationships.

Quality Systems

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

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

The position of Vice President, Regulatory, Quality and Government Affairs is currently vacant, and we are actively seeking to fill this position.

Research and Development

As of December 31, 2006, we had 248 full-time and temporary employees in research and development. Our research and development expenses were $84.5 million in 2006, $71.8 million in 2005 and $68.5 million in 2004.

Employees

As of December 31, 2006, we had 925 full-time employees, of whom 196 hold advanced degrees, 228 were in research and development, 127 were in regulatory, clinical and quality systems, 159 were in sales and marketing, 143 were in general and administrative and 268 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, 2006, 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. We incurred substantial costs of manufacturing these lots in 2005 and expect to incur substantial costs for these lots in the future. Moreover, a variety of factors may affect our ability to make accurate forecasts regarding our operating results. For example, our new blood screening products and 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

diagnostic products on projections prepared by our distributors of these products and therefore we are dependent upon the accuracy of those projections. 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.

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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 mircoorganisms. Commercial product sales by Novartis accounted for 43% of our total revenues for 2006 and 42% of our total revenues for 2005. As of December 31, 2006, we believe our collaboration agreement with Novartis will terminate in 2012 unless extended by the 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. We do not know what effect, if any, Novartis recent acquisition of Chiron, our original corporate partner, will have on our blood screening collaboration.

In February 2001, we commenced an arbitration proceeding against Chiron 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 our products will terminate in 2010. In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. We recently 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 market successfully our products, our product sales will decrease.

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

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

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 unless extended by the development of new products under the agreement, in which case it will expire upon the later 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 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 believe that our experience with the TIGRIS instrument is consistent with the general experience for comparable diagnostic instruments. We have initiated an in-service reliability improvement program for our TIGRIS instrument and a number of improvements have been installed at customers sites. If the continuous improvement program does not result in improved instrument reliability, we could incur greater than anticipated service expenses and market acceptance of the instrument could be adversely affected. We also have committed significant resources to our continuous improvement program. However, these additional resources may not result in the desired improvements in the reliability of our TIGRIS instrument. Additionally, failure to resolve reliability issues as they develop could materially damage our reputation and prevent us from retaining our existing customers and attracting new customers.

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. For example, in October 2005, the FDA notified us that it

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considers our TIGRIS instrument to be used for screening donated human blood with the Procleix Ultrio assay not substantially equivalent to our already cleared eSAS. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. More recently, on July 19, 2006, we received a complete review letter from the FDA setting forth questions regarding the prior-approval supplement to our BLA for the WNV assay, adding the TIGRIS instrument. In August 2006, we responded to the FDA s questions. Both the BLA supplement and the 510(k) application must be approved before licensed testing with the WNV assay can begin on the TIGRIS instrument. There can be no assurance that these approvals will be received.

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.

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 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 the Clinical Laboratory Improvement Amendments of 1988, or 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, which would harm our operating results.

We face intense competition, and our failure to compete effectively could decrease our revenues and harm our profitability and results of operations.

The clinical diagnostics industry is highly competitive. Currently, the majority of diagnostic tests used by physicians and other health care providers are performed by large reference, public health and hospital laboratories. We expect that these laboratories will compete vigorously to maintain their dominance in the diagnostic testing market. In order to achieve market acceptance of our products, we will be required to demonstrate that our products provide accurate, cost-effective and time saving alternatives to tests performed by traditional laboratory procedures and products made

by our competitors.

In the markets for clinical diagnostic products, a number of competitors, including Roche, Abbott, Becton Dickinson, Siemens and bioMérieux, 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 than we are to respond quickly to new or emerging

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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.

Competitors may make rapid technological developments which 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. Abbott recently entered into a definitive agreement to sell its diagnostics division, which markets these products, to General Electric. 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. 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. To the extent that 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.

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.

We expect the blood screening market ultimately to transition from pooled testing of large numbers of donor samples to smaller pool sizes and, ultimately, 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 the blood screening assay will decrease upon

the adoption of smaller pool sizes and individual donor testing. We are not able to predict accurately the 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 if these testing changes are implemented.

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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. Our blood screening collaboration with Novartis accounted for 48% of our total revenues for 2006 and 52% of our total revenues for 2005. 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 2006. In addition, Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated and various state and city public health agencies accounted for an aggregate of 20% of our total revenues in each of 2006 and 2005. 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 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 430 United States and foreign patents covering our products and technologies as of December 31, 2006, 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 October 16, 2023 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

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individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market and execute our business strategies.

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

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. From time-to-time in the ordinary course of business we receive communications from third parties calling our attention to patents or other intellectual property rights owned by them, with the implicit or explicit suggestion that we may need to acquire a license of such rights. We have faced in the past and may face in the future, patent infringement lawsuits by companies that control patents for products and services similar to ours or other lawsuits alleging infringement by us of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management s attention from other business concerns. The cost of this litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

Recently, we have been involved in a number of patent 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. We are not named as a party to Digene s arbitration and Digene has declined our request to join the arbitration. 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 seeks a declaratory judgment that the supply and purchase agreement is valid and does not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene.

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) (the 276 patent), originally issued to Chiron (now Novartis). The first interference is between Novartis and Centocor, Inc., and pertains to Centocor s U.S. Patent Application No. 06/693,866 (Cloning and Expression of HTLV-III DNA) (the 866 application). The second interference is 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)) (the 410 application). Novartis is the junior party in both interferences. If Novartis does not prevail in the proceedings, one or both of the senior parties 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 outcomes of these matters.

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

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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, 2006, we had approximately $231.0 million of long-lived assets, including $18.4 million of capitalized software relating to our TIGRIS instrument, goodwill of $18.6 million, a $2.5 million investment in Molecular Profiling Institute, Inc., a $7.0 million investment in Qualigen, Inc., and $49.9 million of capitalized license and manufacturing access fees, patents and purchased intangibles. Additionally, we had $65.7 million of land and buildings, $14.8 million of leasehold improvements, $0.6 million of construction in-progress and $53.5 million of equipment and furniture and fixtures. 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 taxes.

In September 2006, the SEC released Staff Accounting Bulleting (SAB) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. SAB No. 108, which is effective for fiscal years ending after November 15, 2006, provides guidance on how the effects of prior year uncorrected misstatements, previously deemed to be immaterial, must be considered and adjusted during the current year. In SAB No. 108, the SEC acknowledged that diversity in practice existed in how to accumulate and quantify misstatements, and provided companies new guidance in this area. As a result of applying this new SEC rule to an inventory under-valuation that we identified in 2003, we adjusted our 2006 opening retained earnings by $3.9 million and our financial results for the first three quarters of 2006, which negatively impacted net income for the nine-months ended September 30, 2006 by $0.9 million ($0.02 per diluted share).

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. The SEC required us to adopt this

statement on January 1, 2006. This statement eliminates the ability to account for stock-based compensation using the intrinsic value method allowed under Accounting Principles Board No. 25 and requires these transactions to be recognized as compensation expense in the statement of income based on the fair values on the date of grant, with the compensation expense recognized over the period in which an employee or director is required to provide service in exchange for the stock award. This new requirement negatively impacted our earnings

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by $13.6 million ($0.26 per diluted share) for the year-ended December 31, 2006 and will negatively impact our future earnings.

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, including with our industrial collaborators. 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, such as our TIGRIS instrument. The development of a new instrument platform, if any, in turn may require the modification of existing assays for use with the new instrument, and additional regulatory approvals.

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market 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. For example, we have experienced delays in FDA clearance for our TIGRIS instrument for blood screening with the Procleix Ultrio assay and with respect to our regulatory application to run our previously approved WNV assay on the TIGRIS instrument. Regulatory clearance or approval of these and any other new products 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.

We recently entered into 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.

In July and August 2005, and November 2006, we entered into collaboration agreements to develop NAT products for detecting microorganisms in selected water applications and for microbiological and virus monitoring in the biotechnology, pharmaceutical and food manufacturing industries. Our experience to date has been primarily focused on developing products for the clinical diagnostic and blood screening markets. 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 make significant investments to ensure that any products we develop perform properly, are cost-effective and adequately address customer needs. Even if we develop products for commercial use in these markets, any products we develop may not be accepted in these markets, may be subject to competition and may be subject to other risks and uncertainties associated with these markets. 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 from traditional culture and other testing methods 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, there is no guarantee that we will be able to successfully develop commercially viable products for application in industrial testing or any other new markets.

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

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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.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including, for example, for research and development to successfully develop new technologies and products, and to acquire new technologies, products or companies.

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 effect 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.

We have only one third-party manufacturer for each of our instrument product lines, which exposes us to increased risks associated with 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 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 product shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation.

Further, our business would be harmed if we fail to manage effectively the manufacture of our instruments. Because we place orders with our manufacturers based on our 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.

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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 to be used in industrial applications, 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 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 and clinical and validation testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates and the initiation of new development programs.

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 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 and correct the problem. 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.

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Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 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 for 2006 and 78% of our international revenues for 2005. Novartis has responsibility for the international distribution of our blood screening products, which includes sales in France, Australia, Singapore, New Zealand, South Africa, Italy and other countries. Our sales in France and Japan that were not made through Novartis accounted for 5% of our international sales in 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. Other than Canada, our sales are currently denominated in United States dollars. 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, or in Japan until we are able to offer an assay that meets particular Japanese requirements for screening for 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. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion has led and will lead to lower gross margin percentages.

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

We sell our clinical diagnostic products primarily to large reference laboratories, public health institutions and hospitals, substantially all of which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other domestic and international 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.

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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.

Disruptions in the supply of raw materials and consumable goods 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 in a raw material, either unknown to us or incompatible with our products, could significantly reduce 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 future 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 litigation with Digene regarding the supply and purchase agreement. There can be no assurance that the matter will be resolved in our favor.

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 and the chemiluminescence technology we use in our products is based on technology licensed by our consolidated subsidiary, Molecular Light Technology Limited, from the University of Wales College of Medicine. 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 will 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.

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

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

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 sales, marketing, research, product development, engineering, or technical 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.

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.

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. 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

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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 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.

We may not successfully integrate acquired businesses or technologies.

Through a series of transactions concluding in May 2005, we acquired all of the outstanding shares of Molecular Light Technology Limited and its subsidiaries and, in the future, we may acquire additional businesses or technologies. Managing this acquisition and 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 results in significant goodwill or other 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.

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

Growth in our business has placed and may continue to place a significant strain on our personnel, facilities, management systems and resources. We will need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce. We will have to maintain close coordination among our various departments. If we fail to effectively manage our growth, it could adversely affect our ability to pursue business opportunities and expand our business.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we implemented a new 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 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***

There are no material written comments that we received from the SEC staff 180 days or more before the end of the fiscal year ended December 31, 2006 that remain unresolved. We did receive comments from the SEC staff on December 22, 2006 pertaining to our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. On

January 16, 2007, we submitted our responses to the comments.

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. We recently completed construction of an additional building that 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

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space can be used to accommodate future growth. First phase construction costs were approximately $46 million for this facility. These costs were capitalized as incurred and depreciation commenced upon our move-in during May 2006. Our subsidiary MLT owns a 23,000 square-foot facility in Cardiff, United Kingdom.

We also lease the following additional facilities:

Leased Facilities

Location	Size	Term of Lease
Rancho Bernardo Facility San Diego, California	93,646 square feet	Lease expires in February 2008 with three five-year renewal options.
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

On December 4, 2006, Digene Corporation filed a demand for binding arbitration against F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc., or, together, Roche, with the International Centre for Dispute Resolution of the American Arbitration Association in New York. Digene s arbitration demand challenges the validity of our February 2005 Supply and Purchase Agreement with Roche. Under the supply and purchase agreement, Roche manufactures and supplies us with human papillomavirus 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. We are not named as a party to Digene s arbitration and Digene has declined our request to join the arbitration.

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 seeks a declaratory judgment that the supply and purchase agreement is valid and does not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene.

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 matters will be resolved in our favor.

Bayer Corporation (now Siemens Medical Solutions Diagnostics, Inc.)

In June 2006, we entered into a Short Form Settlement Agreement with Bayer HealthCare LLC and Bayer Corp., or, together, 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 previously 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.

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Pursuant to the Settlement Agreement, Bayer paid us an initial license fee of $5.0 million in August 2006. Additionally, Bayer agreed to pay us approximately $10.3 million as a one-time royalty if Bayer sells any product subject to our patents covered by the Settlement Agreement on or after January 1, 2007, and Bayer also agreed to pay us approximately $16.4 million as a one-time royalty if Bayer sells any product subject to our patents on or after January 1, 2008. Subject to these two royalty payments, Bayer s rights to the related patents will be fully paid-up and royalty free.

During 2006, we recorded the $5.0 million initial license fee from Bayer as royalty and license fee revenue, and recorded approximately $2.0 million of additional G&A expenses for a payment to our outside litigation counsel in connection with the settlement.

In accordance with the Settlement Agreement, Bayer dismissed its October 4, 2005 demand for arbitration and a related lawsuit. The parties also submitted a stipulated final award in the original arbitration proceeding we filed against Bayer in November 2002, adopting the arbitrator s prior interim and supplemental awards, except that Bayer is 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, 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.

On December 31, 2006, Bayer completed the sale of its diagnostics division to Siemens AG and assigned the Settlement Agreement to Siemens Medical Solutions Diagnostics, Inc. We believe that Bayer retained the obligation to make the 2007 and 2008 royalty payments, if due. On January 8, 2007, Siemens notified Bayer and us in writing that it is making and selling products subject to the license we granted and that Siemens believed the 2007 royalty of $10.3 million was due from Bayer. We received Bayer s payment on January 31, 2007.

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, 2006.

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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.

2005	High	Low
First Quarter	$ 52.65	$ 42.65
Second Quarter	$ 53.14	$ 35.40
Third Quarter	$ 49.96	$ 36.07
Fourth Quarter	$ 50.14	$ 38.36

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

As of February 16, 2007, there were approximately 7,231 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, 2006	1,752	$ 47.05		$
November 1-30, 2006	7,147	48.54		
December 1-31, 2006				
Total	8,899(1)	$ 48.25		$

(1) During the fourth quarter of 2006, we repurchased and retired 8,899 shares of our common stock, at an average price of $48.25, 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, 2006, we had an aggregate of 193,808 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, 2006 and, with respect to our consolidated balance sheets, at December 31, 2006 and 2005 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, 2003 and 2002 and the balance sheet data as of December 31, 2004, 2003, and 2002 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.

	2006	2005	2004	2003	2002
	(In thousands, except per share data)				
Statement of income data for the years ended December 31:					
Revenues:					
Product sales	$ 325,307	$ 271,650	$ 222,560	$ 188,645	$ 139,932
Collaborative research revenue	15,937	25,843	27,122	15,402	11,032
Royalty and license revenue	13,520	8,472	20,025	3,144	4,633
Total revenues	354,764	305,965	269,707	207,191	155,597
Operating expenses:					
Cost of product sales	103,882	83,900	59,908	45,458	53,411
Research and development	84,545	71,846	68,482	63,565	47,045
Marketing and sales	37,096	31,145	27,191	22,586	18,199
General and administrative	44,936	32,107	31,628	23,233	20,995
Total operating expenses	270,459	218,998	187,209	154,842	139,650
Income from operations	84,305	86,967	82,498	52,349	15,947
Net income[(1)]	$ 59,498	$ 60,089	$ 54,575	$ 35,330	$ 13,007
Net income per share:					
Basic	$ 1.15	$ 1.19	$ 1.10	$ 0.74	$ 0.27
Diluted	$ 1.12	$ 1.15	$ 1.06	$ 0.72	$ 0.27
Weighted average shares outstanding:					
Basic	51,538	50,617	49,429	47,974	47,600
Diluted	53,101	52,445	51,403	49,137	47,610
Balance sheet data as of December 31:					
Cash, cash equivalents and short-term investments	$ 289,913	$ 220,288	$ 193,826	$ 156,306	$ 107,960
Working capital	342,062	262,375	234,202	169,000	115,288

Total assets	623,839	510,236	411,082	324,741	258,157
Stockholders equity[2]	570,208	447,373	361,029	270,375	215,578

(1) Net income in 2006 of $59.5 million ($1.12 per diluted share) included stock-based compensation expense that we recorded as a result of the adoption of Statement of Financial Accounting Standards No. 123(R), Share-Based Payment, on January 1, 2006. During 2006, this expense totaled $21.3 million before income taxes and $13.6 million net of income taxes for the year. For 2005 and 2004, net income including pro forma stock-based compensation expense was $45.3 million ($0.86 per diluted share) and $41.9 million ($0.82 per diluted share), respectively.

(2) Effective January 1, 2006, we adopted Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements which is explained in Note 1 to our consolidated financial statements.

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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, 2006, 2005 and 2004 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 24 years of nucleic acid detection research and product development experience, 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 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 future 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, and for measuring markers for prostate cancer.

Recent Events

Financial Results

Product sales for 2006 were $325.3 million, compared to $271.7 million in 2005, an increase of 20%. Total revenues for 2006 were $354.8 million, compared to $306.0 million in 2005, an increase of 16%. Net income for the year was $59.5 million ($1.12 per diluted share), compared to $60.1 million ($1.15 per diluted share) in 2005, a decrease of 1%. Net income for 2006 included stock-based compensation expense that we recorded as a result of the adoption of Statement of Financial Accounting Standards, or SFAS, No. 123(R), Share-Based Payment, on January 1, 2006.

During 2006, this expense totaled $21.3 million before income taxes and $13.6 million net of income taxes for the year.

Corporate Collaborations

In November 2006, we entered into an exclusive development and supply agreement with 3M Company, or 3M, to develop, manufacture and market innovative NAT products to enhance food safety and increase the efficiency of testing for food producers. Under the terms of the agreement, 3M is responsible for developing sample

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processing methods that will be used with our NAT assays. 3M will be responsible for obtaining the necessary regulatory approvals and commercializing the products. We are responsible for assay development and manufacturing. 3M has agreed to make milestone payments to us based on technical progress, and to provide funding for assay development.

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.

In May 2006, we amended our license and collaboration agreement with DiagnoCure Corporation. 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 certain genetic markers that we acquired under our license agreement with Corixa Corporation and we agreed to make monthly payments to DiagnoCure for these services, and (iv) we agreed to amend our regulatory timeline obligations for an *in vitro* diagnostic assay for PCA3.

In April 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. In May 2006, pursuant to the terms of this agreement, we paid a license fee of $0.5 million to the University of Michigan. We recorded the license fee as research and development, or R&D, expense, since we have not yet determined technological feasibility and do not currently have alternative future plans to use this technology.

In April 2006, pursuant to our November 2004 License and Preferred Stock Acquisition Agreement with Qualigen, Inc. and based upon the results of an 18-month technical evaluation study, we exercised our option to obtain an exclusive worldwide license to Qualigen technology to develop a novel NAT system based on Qualigen s Food and Drug Administration, or FDA, approved FastPack immunoassay system. If development of this instrument is successful, the new system, known as a closed unit-dose assay, or CUDA, system, would use our NAT technologies to detect microorganisms and genetic mutations at the point of sample collection. As a result of the option exercise, we paid Qualigen approximately $7.0 million 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. We may also pay Qualigen up to $3.0 million based on achievement of development milestones under the license agreement and agreed to pay Qualigen royalties on sales of any product we develop under the agreement. We recorded this investment as an intangible asset on a cost basis, and will review the asset for impairment on an ongoing basis.

Supply 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., or Roche. Under this agreement, Roche agreed to manufacture and supply to us 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 and agreed to pay $10.0 million upon the occurrence of certain future commercial events, but not later than December 1, 2008.

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. Digene s arbitration demand asserts 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. We believe that the supply and purchase agreement is valid and that our purchases of HPV oligonucleotide

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products under the supply and purchase agreement are and will be in accordance with applicable law. 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 seeks a declaratory judgment that the supply and purchase agreement is valid and does not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene.

Product Development

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 95 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. During the second quarter of 2006, two clinical laboratory customers in the United States completed validation of Transcription-Mediated Amplification, or TMA, assays for PCA3 and PSA, or prostate specific antigen, using our analyte specific reagents, or ASRs, and general purpose reagents, or GPRs, and began offering these tests to physicians and reporting patient results, employing a PCA3 to PSA ratio.

In October 2006, the FDA granted marketing approval for the Procleix Ultrio assay to run on the Procleix enhanced semi-automated system, or eSAS. 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, and to detect the presence of HBV. However, the initial pivotal study for the Procleix Ultrio assay was not designed to, and did not, demonstrate yield, defined as HBV-infected blood donations that are negative based on serology tests for HBV surface antigen and core antibody. Based on discussions with the FDA, we and Novartis expect to initiate a post-marketing study to demonstrate HBV yield in order to gain a donor-screening claim. We expect this study to begin in early 2007.

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.

Also, in October 2006, the FDA granted marketing clearance to run our individual APTIMA assays for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* on the fully automated TIGRIS instrument. The two amplified nucleic acid tests, which were previously approved to run on eSAS, detect the microorganisms that cause the most common bacterial sexually transmitted diseases in the United States. In August 2006, the FDA granted marketing clearance to use the APTIMA Combo 2 assay to test two additional kinds of patient samples for chlamydia and gonorrhea on our fully automated TIGRIS instrument.

In March 2006, we began shipment to Novartis of FDA-approved and labeled Procleix WNV assays for use with eSAS. In April 2006, we submitted to the FDA a prior-approval supplement to our WNV assay Biologics License Application, or BLA, adding the TIGRIS instrument and we submitted an application for 510(k) clearance of the TIGRIS instrument for use with the WNV assay at the same time. In June 2006, we received questions from the FDA regarding our 510(k) application for the TIGRIS instrument. In August 2006, we responded to the FDA s questions presented in a complete review letter we received in late July 2006, which set forth questions regarding the prior-approval supplement to the BLA adding the TIGRIS instrument. Both the BLA supplement and the 510(k) application must be approved before licensed testing with the WNV assay can begin on the TIGRIS instrument. There can be no assurance that these approvals will be received.

In March 2006, in response to FDA comments, we withdrew use of TriPath s liquid Pap transport media from the APTIMA *Chlamydia trachomatis* assay 510(k) application. We are deferring further FDA applications concerning use of our assays with the TriPath media.

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Litigation Settlement

Bayer Corporation (now Siemens Medical Solutions 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. Additionally, Bayer agreed to pay approximately $10.3 million as a one-time royalty if Bayer sells any product subject to our patents covered by the Settlement Agreement on or after January 1, 2007, and Bayer also agreed to pay approximately $16.4 million as a one-time royalty if Bayer sells any product subject to our patents on or after January 1, 2008. Subject to these two royalty payments, Bayer s rights to the related patents will be fully paid-up and royalty free.

During 2006, we recorded the $5.0 million initial license fee from Bayer as royalty and license fee revenue, and recorded approximately $2.0 million of additional general and administrative, or G&A, expenses for a payment to our outside litigation counsel in connection with the settlement.

In accordance with the Settlement Agreement, Bayer dismissed its October 4, 2005 demand for arbitration and a related lawsuit. The parties also submitted a stipulated final award in the original arbitration proceeding we filed against Bayer in November 2002, adopting the arbitrator s prior interim and supplemental awards, except that Bayer is 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, 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.

On December 31, 2006, Bayer completed the sale of its diagnostics division to Siemens AG and assigned the Settlement Agreement to Siemens Medical Solutions Diagnostics, Inc. We believe that Bayer retained the obligation to make the 2007 and 2008 royalty payments, if due. On January 8, 2007, Siemens notified Bayer and us in writing that it is making and selling products subject to the license we granted and that Siemens believed the 2007 royalty of $10.3 million was due from Bayer. We received Bayer s payment on January 31, 2007.

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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 that serve as the analytical platform 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 2006, product sales, collaborative research revenues and royalty and license revenues equaled 92%, 4% and 4%, respectively, of our total revenues of $354.8 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. Our share of net revenues from commercial sales of assays that include a test for HCV is 45.75% under our collaboration agreement with Novartis. With respect to commercial sales of blood screening assays under our collaboration agreement with Novartis that do not include a test for HCV, such as the WNV assay, we receive 50% of net revenues after deduction of appropriate expenses. Our costs related to these products after commercialization primarily include 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 eSAS to screen donated human blood. In the first quarter of 2006, upon shipment of FDA-approved and labeled product, we changed the recognition of prospective sales of the WNV assay for use on eSAS from collaborative research revenue to product sales.

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

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Royalty and license revenue

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

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. During 2005, our manufacturing facilities produced large-scale development lots for our WNV and Procleix Ultrio assays. There were no large-scale blood screening development lots produced in 2006. The majority of costs associated with these development lots are classified as 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, below its potential capacity for the foreseeable future. A portion of this available capacity is utilized for R&D activities as new product offerings are developed for commercialization. As a result, certain operating costs of our blood screening 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 $9.7 million and $9.0 million, during 2006 and 2005, respectively. Under our collaboration agreement with Novartis, we sell TIGRIS instruments to them at prices that approximate cost. These instrument sales, therefore, negatively impact our gross margin percentage in the periods when they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

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 and mid-volume laboratories, as well as for the development of assays for PCA3 and HPV and for industrial applications.

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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, the collectibility of accounts receivable, valuation of inventories, long-lived assets, including patent costs and capitalized software, income taxes and valuation of stock-based compensation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

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

Revenue recognition

We record shipments of our 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 third-party 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 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 may also include the sales or rental value 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 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 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

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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.

Collectibility of accounts receivable

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. Credit losses historically have been minimal and within management s expectations. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required.

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.

Historically, changes to inventories valuation reserves in subsequent periods have not materially affected cost of product sales. For 2006, 2005 and 2004, total gross charges to our inventories reserves have not impacted gross margin, as a percentage of sales, by more than 2.5%. We believe that similar charges to estimated inventories reserves, and the related effect on gross margins, are reasonably likely in the future.

Valuation of goodwill

We assess the impairment of goodwill 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 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. To date, there have been no indicators of impairment.

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Capitalized software costs

We capitalize costs incurred in the development of computer software related to products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product. At December 31, 2006, capitalized software development costs related to products for use on our TIGRIS instrument totaled $18.4 million, net of accumulated amortization.

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

Impairment of long-lived assets

We assess the recoverability of long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the fair value to the carrying value.

Income taxes

Our income tax returns are based on calculations and assumptions that are subject to examination by various tax authorities. Currently, our United States federal and California income tax returns for years through 2004 are under examination. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of these examinations and any future examinations in determining the adequacy of our provision for income taxes. As part of our assessment of potential adjustments to our tax returns, we increase our current tax liability to the extent an adjustment would result in a cash tax payment or decrease our deferred tax assets to the extent an adjustment would not result in a cash tax payment. We review, at least quarterly, the likelihood and amount of potential adjustments and adjust the income tax provision, the current tax liability and deferred taxes in the period in which the facts that give rise to a revision become probable and estimable. Although we believe that the estimates and assumptions supporting our assessments are reasonable, adjustments could be materially different from those that are reflected in historical income tax provisions and recorded assets and liabilities.

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

Stock-based compensation

On January 1, 2006, we adopted SFAS No. 123(R). 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. Our 2006 financial statements reflect the impact of SFAS No. 123(R). We adopted the provisions of SFAS No. 123(R) 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 the portion of stock-based payment awards that is ultimately expected to vest, which coincides with the award holder s requisite service period. Estimated compensation expense for awards outstanding on January 1, 2006 are 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), we elected to value our share-based payment awards granted beginning in 2006 using the Black-Scholes-Merton option-pricing model, which was previously used for our 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 accordance with FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans. Effective January 1, 2006, in conjunction with the adoption of SFAS No. 123(R), we now amortize all new grants as expense

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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.

The determination of fair value of stock-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. Our stock options and the option component of our Employee Stock Purchase Plan, or ESPP, shares have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

The expected term of stock options granted represents the period of time that they are expected to be outstanding. Historically, we determined the expected term of stock options based on either Section 16 insider reported data from a select group of peer companies (in 2005) or a period that was equivalent to the vesting period (in 2004). In May 2006, our stockholders approved an amendment and restatement of The 2003 Incentive Award Plan that decreased the maximum contractual term of prospective option grants from ten years to seven years. Corresponding with this change, we revised our determination of the expected term of options by applying a weighted-average calculation combining the average life of options that have already been exercised with the estimated life of all unexercised options.

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. Our stock-based compensation expense is based on awards ultimately expected to vest. In 2006, we reduced stock-based compensation expense to allow for estimated forfeitures based on historical experience. In our pro forma information required under SFAS No. 123 for the periods prior to 2006, we accounted for forfeitures as they occurred.

New accounting requirements

Adoption of SAB No. 108

In September 2006, the Securities and Exchange Commission, or SEC, released Staff Accounting Bulleting No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, or SAB No. 108. SAB No. 108, which is effective for fiscal years ending after November 15, 2006, provides guidance on how the effects of prior year uncorrected misstatements, previously deemed to be immaterial, must be considered and adjusted during the current year.

In SAB No. 108, the SEC acknowledged that diversity existed in how to accumulate and quantify misstatements, and provided companies new guidance in this area. SAB No. 108 requires companies to assess the effects of uncorrected misstatements using each of two methods. The first method, known as the rollover method, quantifies a misstatement based on the effect of correcting the misstatement that exists in the current year statement of income. SAB No. 108 also requires companies to assess the materiality of correcting the misstatement using a technique known as the iron curtain method. The iron curtain method quantifies a misstatement existing in the balance sheet based on the effects of correcting it, on a cumulative basis, at the end of the current year, regardless of in which year the misstatement originated. In addition, SAB No. 108 requires companies to use the iron curtain method to evaluate the materiality of the cumulative misstatement to prior years statements of income.

If a misstatement made in a prior year is deemed immaterial under a company s historical assessment approach, but is deemed material under the additional method, the newly instituted SAB No. 108 allows companies, in the year of adopting the standard, to correct the misstatement by adjusting the opening balance of stockholders equity. SAB No. 108 also requires the adjustment of any prior quarterly financial statements in SEC filings within the fiscal

year of adoption for the effects of such misstatements. This adjustment does not require reports previously filed with the SEC to be amended.

Historically, we have assessed all misstatements under the rollover method. In applying this new standard, we were required to review any uncorrected misstatements relating to our 2004 and 2005 financial statements. As a result of this review, one misstatement that we previously concluded was not material, under the rollover method, was determined to be material under the iron curtain method. This misstatement is described below.

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In March 2003, we completed an analysis of the appropriate levels of labor and overhead to be included in our costs of inventories. As a result of this analysis, we concluded that inventories had been understated, and cost of product sales therefore overstated, by approximately $11.4 million over a period of several years, primarily due to the substantial growth of our manufacturing operations. More specifically, the analysis concluded that costs such as quality control and manufacturing equipment support, which historically had been included in cost of product sales as a period expense, should have first been capitalized into inventories. Rather than recording the revaluation of inventories as a one-time benefit to our statement of income in 2003, which would have materially overstated net income, we chose to amortize the increase in the value of inventories over six years. To correct the under-valuation of inventories in this manner, we increased the value of inventories and established a revaluation reserve equal to the increase in the value of the inventories. The six-year amortization period was chosen because the under-valuation of inventories had accumulated over many years, because some of the inventories involved had a long economic life, and to ensure that increasing the value of inventories would not materially affect earnings in any future reporting period. As a result of utilizing this approach, we were amortizing the inventories revaluation reserve, as a reduction to our cost of product sales, by up to $2.0 million each year beginning in 2003. The impact on our financial statements for 2004 and 2005 was not material, when assessed under the rollover method. As required under the iron curtain method, we reassessed the materiality of the unamortized balance as of December 31, 2005 on our 2005 reported financial statements, as if the entire reserve on the balance sheet, $6.5 million, was corrected through the 2005 statement of income. As a result of utilizing the iron curtain methodology of correcting the under-valuation of inventories, we concluded that the effect would be material.

In accordance with the transition guidance provided by SAB No. 108, we adjusted our 2006 opening retained earnings by the net impact of the under-valuation of inventories, which was $3.9 million. Further, we recorded an adjustment to increase the 2006 opening balances of inventories by $6.5 million and our tax accounts by $2.6 million. We also recast our financial results for the first three quarters of 2006, to reverse a total of $1.5 million of the amortization of the revaluation reserve. The recast quarterly financial information is included in Notes 1 and 12 to our financial statements.

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Had the re-valuation of inventories been recorded as a benefit to the statements of income in cost of product sales prior to 2003, our financial results would have been adjusted as follows (in thousands, except per share data):

	Years Ended December 31,		
	2005	2004	2003
As reported:			
Cost of product sales	$ 83,900	$ 59,908	$ 45,458
Income tax expense	31,605	30,004	19,766
Net income	60,089	54,575	35,330
Net income per share			
Basic	$ 1.19	$ 1.10	$ 0.74
Diluted	$ 1.15	$ 1.06	$ 0.72
Adjustment:			
Cost of product sales	$ 1,990	$ 1,990	$ 957
Income tax expense	(805)	(806)	(388)
Net income	(1,185)	(1,184)	(569)
Percent of reported net income	2.0 %	2.2 %	1.6 %
Net income per share			
Basic	$ (0.02)	$ (0.02)	$ (0.01)
Diluted	$ (0.02)	$ (0.02)	$ (0.01)
As adjusted:			
Cost of product sales	$ 85,890	$ 61,898	$ 46,415
Income tax expense	30,800	29,198	19,378
Net income	58,904	53,391	34,761
Net income per share			
Basic	$ 1.16	$ 1.08	$ 0.72
Diluted	$ 1.12	$ 1.04	$ 0.71

Future accounting requirements

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 are evaluating whether the adoption of FIN No. 48 will have a material effect on our statements of income. We do not anticipate the adoption of FIN No. 48 will have a material effect on our statements of income and effective tax rate in future periods.

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Results of Operations

	Years Ended December 31,			% Change	
	2006	2005	2004	2006/2005	2005/2004
	(In millions, except per share data)				
Statement of income:					
Revenues:					
Product sales	$ 325.3	$ 271.7	$ 222.6	20 %	22 %
Collaborative research revenue	16.0	25.8	27.1	(38)%	(5)%
Royalty and license revenue	13.5	8.5	20.0	59 %	(58)%
Total revenues	354.8	306.0	269.7	16 %	13 %
Operating expenses:					
Cost of product sales	103.9	83.9	59.9	24 %	40 %
Research and development	84.6	71.9	68.5	18 %	5 %
Marketing and sales	37.1	31.1	27.2	19 %	14 %
General and administrative	44.9	32.1	31.6	40 %	2 %
Total operating expenses	270.5	219.0	187.2	24 %	17 %
Income from operations	84.3	87.0	82.5	(3)%	5 %
Total other income, net	8.7	4.7	2.1	85 %	124 %
Income tax expense	33.5	31.6	30.0	6 %	5 %
Net income	$ 59.5	$ 60.1	$ 54.6	(1)%	10 %
Net income per share					
Basic	$ 1.15	$ 1.19	$ 1.10	(3)%	8 %
Diluted	$ 1.12	$ 1.15	$ 1.06	(3)%	8 %
Weighted average shares outstanding					
Basic	51.5	50.6	49.4		
Diluted	53.1	52.4	51.4		

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.

Net income in 2006 of $59.5 million ($1.12 per diluted share) included stock-based compensation expense that we recorded as a result of the adoption of SFAS No. 123(R) on January 1, 2006. During 2006, this expense totaled $21.3 million before income taxes and $13.6 million net of income taxes for the year. For 2005 and 2004, net income including pro forma stock-based compensation expense was $45.3 million ($0.86 per diluted share) and $41.9 million ($0.82 per diluted share), respectively.

Product sales

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 sales 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 HIV-1/HCV/HBV (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

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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, which includes an assay for HBV that is combined in one test with the HIV-1/HCV assay, grew approximately 22% from 2005 levels, as the Procleix line further penetrated international markets. Diagnostic 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. Average pricing related to our primary APTIMA products remained consistent with 2005 levels.

Product sales increased 22% to $271.7 million in 2005 from $222.6 million in 2004. The $49.1 million increase was principally the result of $13.6 million in higher instrument sales, $22.6 million in higher blood screening sales, and $21.9 million in higher APTIMA assay sales, partially offset by a $6.8 million decrease in PACE product sales. Revenues from all other product sales lines decreased a combined $2.2 million from 2004. Blood screening sales represented $130.0 million, or 48% of product sales in 2005, compared to $95.6 million, or 43% of product sales, in 2004. The increase in blood screening sales during 2005 was principally attributed to increased international Procleix Ultrio assay sales volume and an increase in instrument sales. United States blood donation volume growth in 2005 was relatively flat from 2004. International blood donation volumes increased by 32% from 2004 levels contributing to the international blood screening revenue growth. Further, blood screening product sales for 2005 included approximately $5.4 million due to the recognition of previously deferred revenue related to United States blood screening products shipped to Novartis third party warehouse, rather than directly to Novartis end customers. Diagnostic sales, including assay, instrument, and ancillary sales, represented $141.7 million, or 52% of product sales, in 2005, compared to $126.9 million, or 57% of product sales in 2004. This increase was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions. Average pricing in 2005 for our APTIMA products remained consistent with 2004. The growth in diagnostics revenues was primarily the result of volume increases and the conversion to APTIMA from PACE.

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 decreased 38% in 2006 from 2005. The $9.8 million decrease from the prior year was primarily the result of a $9.1 million decrease in revenue from Novartis related to deliveries of WNV tests on a cost recovery basis (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 decreased 5% in 2005 from 2004. The $1.3 million decrease in collaborative research revenue was primarily the result of a $3.0 million decrease in revenue due to completion of National Institutes of Health, or NIH, funding of our WNV assay development work during 2004, partially offset by a $0.5 million increase in revenue for reimbursement from Novartis for WNV assay development costs and $1.3 million in revenue for shipments of dHBV assays and TIGRIS instrument lease revenue from Novartis.

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 claim use on the TIGRIS instrument. Also, milestone payments from 3M are due to us in the future 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

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part, on our ability to initiate and maintain relationships with potential and current collaborative partners. These relationships may not be established or maintained and current collaborative research revenue may decline.

Royalty and license revenue

Royalty and license revenue increased 59% in 2006 from 2005. The $5.0 million increase in royalty and license revenue from last year 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 decreased 58% in 2005 from 2004. The $11.5 million decrease in royalty and license revenue during 2005 was principally attributed to (i) $7.0 million in license fees earned from Tosoh in 2004 as part of our non-exclusive licensing agreement relating to NAT technologies effective in January 2004, (ii) a $6.5 million milestone payment from Chiron in 2004 as we began clinical trial testing of the Procleix Ultrio assay on our TIGRIS instrument in the United States, effective in the first quarter of 2004, and (iii) a $3.2 million decrease in net license income from Bayer for the licensing of rights to certain patented technology. These decreases were partially offset by a $3.9 million increase in license fee revenue recognized from bioMérieux s affiliates in 2005, pursuant to the terms of our September 2004 agreement with bioMérieux, and a $1.4 million increase in our share of royalties from Novartis based upon Novartis agreement with Laboratory Corporation of America, or LabCorp, for use of Novartis HCV intellectual property for NAT used in screening plasma donations in the United States.

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

Cost of product sales increased 40% in 2005 from 2004. The $24.0 million increase was principally attributed to increased sales of TIGRIS instruments and spare parts to Novartis ($11.9 million), higher blood screening shipments to international markets ($7.9 million), higher APTIMA shipments ($3.0 million) and the amortization of capitalized software development costs related to our TIGRIS instrument ($0.8 million), which began in the second quarter of 2004.

Our gross profit margin as a percentage of product sales decreased to 68% in 2006, from 69% in 2005 and 73% in 2004. The decrease in gross profit margin percentage in 2006 from 2005 was principally attributed to 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. The 2005 percentage decrease from 2004 was primarily the result of increased sales of lower margin products, including TIGRIS instruments and spare parts, higher international sales of blood screening products and the amortization of capitalized software development costs.

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.

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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 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).

R&D expenses increased 5% in 2005 from 2004. The $3.4 million increase in R&D spending was primarily due to higher staffing levels to support development projects ($7.0 million), such as prostate cancer and HPV, and an increase in development lot production ($1.6 million), partially offset by reductions in clinical trials for blood screening products ($3.0 million), outside services related to TIGRIS instrument development costs ($1.5 million), and lab supplies ($0.4 million).

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. 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 levels to support product sales growth ($1.6 million), and an increase in spending for marketing research and materials ($0.7 million).

Marketing and sales expenses increased 14% in 2005 from 2004. The $3.9 million increase in marketing and sales expenses was primarily due to an increase in salaries, benefits, commissions and other personnel related costs in our marketing, sales, and technical service organization ($3.2 million), together with an increase in spending for market research and industry conventions to help support the TIGRIS instrument and to assess new market opportunities, such as prostate cancer and HPV ($0.6 million).

General and administrative

Our G&A expenses include personnel costs for finance, legal, strategic planning and business development, public relations and human resources, as well as professional fees, such as expenses for legal, patents and auditing services. 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.

G&A expenses increased 2% in 2005 from 2004. The $0.5 million increase in G&A expenses was primarily the result of an increase in salaries, benefits and other personnel related expenses ($1.4 million) and an increase in recruiting and relocation fees ($0.7 million). These increases were partially offset by a $1.6 million decrease in spending on

professional fees as the costs associated with the Bayer arbitration decreased.

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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 $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.

The $2.6 million net increase in total other income, net, in 2005 from 2004 was primarily due to an increase in interest income resulting from higher average balances of our short-term investments and higher yields on our investment portfolio.

Income tax expense

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.

Income tax expense increased 5% in 2005 from 2004 and our effective tax rate decreased to 34.5% of 2005 pretax income, compared to 35.5% of 2004 pretax income. The decrease in our effective tax rate in 2005 was principally attributed to increased tax-exempt interest income in our investment portfolio and the new tax deduction on qualified production activities provided by the American Jobs Creation Act of 2004.

Liquidity and capital resources

	2006	2005	2004	Amount Change From 2005 to 2006
		(In thousands)		
December 31:				
Cash, cash equivalents and short-term investments	$ 289,913	$ 220,288	$ 193,826	$ 69,625
Working capital	342,062	262,375	234,202	79,687
Current ratio	8:1	6:1	8:1	
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	$ 97,816	$ 85,860	$ 62,284	$ 11,956
Investing activities	(76,004)	(97,103)	(93,712)	(21,099)
Financing activities	33,153	18,696	20,438	14,457
Purchases of property, plant and equipment (included in investing activities above)	(50,760)	(45,386)	(26,021)	5,374

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, 2006, we had $289.9 million of cash and cash equivalents and short-term investments.

The $12.0 million increase in net cash provided by operating activities during 2006 from 2005 was primarily due to higher net income ($13.7 million, after adding back non-cash stock-based compensation expense) and improved

collections of trade accounts receivable ($15.5 million). These increases in net cash provided by operating activities were partially offset by a decrease in accounts payable growth from the acceleration of payments to our vendors in December 2004, immediately prior to our implementation of a new Enterprise Resource Planning, or ERP, software system in January 2005 ($7.8 million), along with the reclassification of stock option income tax benefits from operating to financing activities in accordance with SFAS No. 123(R) ($9.2 million).

The $21.1 million decrease in net cash used in investing activities during 2006 from 2005 included a net decrease in license and manufacturing access fees ($17.7 million) and a decrease in purchases (net of sales) of short-term investments ($7.8 million), partially offset by an increase in capital expenditures ($5.4 million). Our 2006

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growth in capital expenditures was primarily due to the construction of our new building and related telecommunication expenses. 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. Our decrease in license and manufacturing access fees in 2006 was due to a $20.0 million manufacturing fee paid to Roche in May 2005, partially offset by our $7.0 million equity investment in Qualigen in April 2006.

The $14.5 million increase in net cash provided by financing activities during 2006 from 2005 was principally attributed to an increase in proceeds from the exercise of stock options ($5.2 million), tax benefits from employee stock options that have been reclassified from operating activities to financing activities in accordance with SFAS No. 123(R) beginning in January 2006 ($9.2 million), and an increase in the net proceeds from ESPP purchases ($0.5 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 2007, 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, 2006, 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, 2006, we were in compliance with all covenants.

In May 2006, we completed construction of an additional building on our main San Diego campus. This new building 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. First phase construction costs were approximately $45.8 million. These costs were capitalized as incurred and depreciation commenced upon our move-in during May 2006. In November 2004, the FASB issued SFAS No. 151, Inventory Costs an Amendment of Accounting Research Bulletin No. 43, Chapter 4 , or SFAS No. 151, clarifying the accounting for idle facility expense to be recognized as a current-period charge. Costs associated with our San Diego campus are generally allocated based on square feet. Costs that are allocated to expansion space are expensed in the period incurred in accordance with SFAS No. 151.

We implemented a new ERP system that cost approximately $4.9 million in 2004. We incurred $3.3 million and $2.9 million in additional costs during 2005 and 2006, respectively. We expect to incur approximately $2.0 million in costs in 2007 for further enhancements to our ERP system.

Contractual obligations and commercial commitments

Our contractual obligations due to lessors for properties that we lease, as well as amounts due for purchase commitments and collaborative agreements as of December 31, 2006 were as follows (in thousands):

	Total	2007	2008	2009	2010	2011	Thereafter
Operating leases[1]	$ 1,100	$ 863	$ 167	$ 70	$	$	$
Material purchase commitments[2]	27,428	27,428					
Collaborative commitments[3]	16,950	4,050	10,850	1,400	650		
Total[4]	$ 45,478	$ 32,341	$ 11,017	$ 1,470	$ 650	$	$

(1) Reflects obligations on facilities under operating leases in place as of December 31, 2006. Future minimum lease payments are included in the table above.

(2) Amounts represent our minimum purchase commitments from two key vendors for TIGRIS instruments and raw materials used in manufacturing. Of the $17.7 million expected to be used to purchase TIGRIS instruments, we anticipate that approximately $8.8 million will be sold to Novartis.

(3) In addition to the minimum payments due under our collaborative 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.

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Also, we may soon commit to spend up to $6.0 million in R&D costs to develop a new instrument platform designed for mid to low volume customers.

(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.

Additionally, we have liabilities for deferred employee compensation which totaled $2.2 million at December 31, 2006. The payments related to the deferred compensation are not included in the table above since 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 expansion of our San Diego campus, continued R&D of 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 and proceeds from stock option exercises, will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to covenants restricting our operations. 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 $3.9 million annually. 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

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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, 2006 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 2006, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $4.5 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-35.

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

None.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, a control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

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

effective as of the end of 2006.

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

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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, 2006 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, 2006.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Gen-Probe Incorporated

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that Gen-Probe Incorporated maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of 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, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management s assessment that Gen-Probe Incorporated maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Gen-Probe Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 and 2005, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2006 of Gen-Probe Incorporated and our report dated February 5, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 5, 2007

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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 2007 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, 2006 and 2005

Consolidated Statements of Income for each of the three years in the period ended December 31, 2006

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2006

Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2006

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, 2006

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 23, 2007

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 23, 2007
/s/ Herm Rosenman Herm Rosenman	Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 23, 2007
/s/ John W. Brown John W. Brown	Director	February 15, 2007
/s/ Raymond V. Dittamore Raymond V. Dittamore	Director	February 23, 2007
/s/ Mae C. Jemison, M.D Mae C. Jemison, M.D	Director	February 23, 2007
/s/ Armin M. Kessler Armin M. Kessler	Director	February 23, 2007
/s/ Brian A. McNamee, M.B.B.S Brian A. McNamee, M.B.B.S	Director	February 23, 2007
/s/ Phillip M. Schneider	Director	February 23, 2007

Phillip M. Schneider		
/s/ Abraham D. Sofaer	Director	February 23, 2007
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, 2006 and 2005, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, 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, in 2006 the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), Share Based Payment, and Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in the Current Year Financial Statements, (SAB No. 108). The Company used the one time special transition provisions of SAB No. 108 and recorded an adjustment to retained earnings effective January 1, 2006 for correction of prior period misstatements in recording standard cost revaluation adjustments to inventories.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Gen-Probe Incorporated s internal control over financial reporting as of December 31, 2006, 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 5, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 5, 2007

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GEN-PROBE INCORPORATED

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

	December 31	
	2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 87,905	$ 32,328
Short-term investments	202,008	187,960
Trade accounts receivable, net of allowance for doubtful accounts of $670 and $790 at December 31, 2006 and 2005, respectively	25,880	31,930
Accounts receivable other	1,646	1,924
Inventories	52,056	36,342
Deferred income taxes short term	7,247	10,389
Prepaid expenses	11,362	10,768
Other current assets	2,583	3,650
Total current assets	390,687	315,291
Property, plant and equipment, net	134,614	105,190
Capitalized software	18,437	20,952
Goodwill	18,621	18,621
Deferred income taxes long term	2,064	
License, manufacturing access fees and other assets	59,416	50,182
Total assets	$ 623,839	$ 510,236
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	13,586	14,029
Accrued salaries and employee benefits	16,723	14,660
Other accrued expenses	3,320	3,264
Income tax payable	14,075	13,192
Deferred revenue	921	7,771
Total current liabilities	48,625	52,916
Deferred income taxes		5,124
Deferred revenue	3,667	4,333
Deferred rent	128	240
Deferred compensation plan liabilities	1,211	250
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, 52,233,656 and 51,137,541 shares issued and outstanding at December 31, 2006 and 2005, respectively	5	5
Additional paid-in capital	334,184	281,907
Deferred compensation		(5,951)
Accumulated other comprehensive (loss) income	(5)	(1,231)
Retained earnings	236,024	172,643
Total stockholders equity	570,208	447,373
Total liabilities and stockholders equity	$ 623,839	$ 510,236

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		
	2006	2005	2004
Revenues:			
Product sales	$ 325,307	$ 271,650	$ 222,560
Collaborative research revenue	15,937	25,843	27,122
Royalty and license revenue	13,520	8,472	20,025
Total revenues	354,764	305,965	269,707
Operating expenses:			
Cost of product sales	103,882	83,900	59,908
Research and development	84,545	71,846	68,482
Marketing and sales	37,096	31,145	27,191
General and administrative	44,936	32,107	31,628
Total operating expenses	270,459	218,998	187,209
Income from operations	84,305	86,967	82,498
Total other income, net	8,689	4,727	2,081
Income before income taxes	92,994	91,694	84,579
Income tax expense	33,496	31,605	30,004
Net income	$ 59,498	$ 60,089	$ 54,575
Net income per share:			
Basic	$ 1.15	$ 1.19	$ 1.10
Diluted	$ 1.12	$ 1.15	$ 1.06
Weighted average shares outstanding:			
Basic	51,538	50,617	49,429
Diluted	53,101	52,445	51,403

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		
	2006	2005	2004
Operating activities			
Net income	$ 59,498	$ 60,089	$ 54,575
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	27,496	22,606	18,239
Stock-based compensation charges restricted stock	2,462	920	1,142
Stock-based compensation charges all other	21,261		
Stock option income tax benefits	191	8,677	14,035
Excess tax benefit from employee stock options	(9,187)		
Loss on disposal of property and equipment	99	399	377
Changes in assets and liabilities:			
Accounts receivable	6,544	(8,937)	(6,774)
Inventories	(7,798)	(9,048)	(13,621)
Prepaid expenses	(595)	(2,251)	(1,428)
Other current assets	1,683	1,797	(2,333)
Other long term assets	(2,147)	(534)	
Accounts payable	(471)	7,329	(2,535)
Accrued salaries and employee benefits	2,063	2,748	242
Other accrued expenses	(27)	(1,089)	(2,329)
Income tax payable	9,970	12,053	(4,965)
Deferred revenue	(7,516)	(2,363)	2,119
Deferred income taxes	(6,559)	(6,717)	5,567
Deferred rent	(112)	(69)	(14)
Deferred compensation plan liabilities	961	250	
Minority interest			(13)
Net cash provided by operating activities	97,816	85,860	62,284
Investing activities			
Proceeds from sales and maturities of short-term investments	135,861	116,907	159,301
Purchases of short-term investments	(149,012)	(137,841)	(206,822)
Cash paid for acquisition of Molecular Light Technology Limited		(1,539)	(376)
Purchases of property, plant and equipment	(50,760)	(45,386)	(26,021)
Capitalization of intangible assets, including license and manufacturing access fees	(11,460)	(29,117)	(19,836)
Other assets	(633)	(127)	42
Net cash used in investing activities	(76,004)	(97,103)	(93,712)

Financing activities			
Excess tax benefit from employee stock options	9,187		
Repurchase and retirement of restricted stock for payment of taxes	(429)		
Proceeds from issuance of common stock	24,395	18,696	20,438
Net cash provided by financing activities	33,153	18,696	20,438
Effect of exchange rate changes on cash and cash equivalents	612	(623)	515
Net increase (decrease) in cash and cash equivalents	55,577	6,830	(10,475)
Cash and cash equivalents at the beginning of year	32,328	25,498	35,973
Cash and cash equivalents at the end of year	$ 87,905	$ 32,328	$ 25,498
Supplemental disclosure of cash flow information:			
Cash paid for:			
Interest	$ 63	$ 162	$ 34
Income taxes	$ 29,958	$ 16,807	$ 16,030

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, 2003	48,722	5	$ 212,586	$ (538)	$ 343	$ 57,979	$ 270,375
Common shares issued from exercise of stock options	1,178		16,672				16,672
Purchase of common shares through employee stock purchase plan	132		3,766				3,766
Purchase of common shares by board members	3		140				140
Deferred compensation related to grant of restricted stock awards			839	(839)			
Amortization of deferred compensation				273			273
Stock option compensation expense for modification of stock option awards			729				729
Stock option income tax benefits			14,035				14,035
Comprehensive income:							
Net income						54,575	54,575
Unrealized losses on short-term investments, net of income tax benefits of $17					(313)		(313)
Foreign currency translation adjustment					777		777
Comprehensive income							55,039
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
	4		136				136

Purchase of common shares by board members							
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 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 inventories			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

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

Gen-Probe Incorporated (Gen-Probe or the Company) is engaged in developing, manufacturing and marketing nucleic acid probe-based products used for the clinical diagnosis of human diseases and screening donated human blood. The Company also develops and manufactures nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. Gen-Probe s principal end customers are large reference laboratories, public health institutions and hospitals located in North America, Europe and Japan.

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. MLT and its subsidiaries are consolidated into the Company s financial statements one month in arrears. 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, the valuation of inventories and long-lived assets, including capitalized software, license and manufacturing access fees, income taxes, 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 recorded directly as a separate component of stockholders equity under the caption Accumulated other comprehensive (loss) income.

Cash and cash equivalents

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

Short-term investments

Short-term investments are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity. 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.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 9.

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, mortgage-backed securities and corporate bonds.

Fair value of financial instruments

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

Collectibility of accounts receivable

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

Share-based payments

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 s 2006 financial statements reflect the impact of SFAS No. 123(R). The Company adopted the provisions of SFAS No. 123(R) 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 the portion of stock-based payment awards that is ultimately expected to vest, which coincides with the award holder s requisite service period. Estimated compensation expense for awards outstanding on January 1, 2006 are 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 granted beginning in 2006 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 accordance with Financial Accounting Standards Board (FASB) Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans. Effective January 1, 2006, 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. Also, certain of

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 determination of fair value of stock-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 s stock options and the option component of the Company s Employee Stock Purchase Plan (ESPP) shares have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

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 ESPP:

	Stock Option Plans			ESPP		
	2006	2005	2004	2006	2005	2004
Risk-free interest rate	4.8%	4.0%	3.2%	4.4%	3.0%	1.0%
Volatility	42%	49%	63%	40%	48%	60%
Dividend yield						
Expected term (years)	4.5	5.2	4.0	0.5	0.5	0.5
Resulting average fair value	$ 20.75	$ 21.02	$ 18.83	$ 12.76	$ 10.86	$ 9.35

The Company determines the risk-free interest rate that it uses in the Black-Scholes-Merton option-pricing model based upon a constant U.S. Treasury Security with a contractual life that approximates the expected term of the option award.

The Company determines the expected volatility of its stock options granted by taking an average of the Company s historical stock price changes (using daily pricing) and the implied volatility on its traded options, consistent with SFAS No. 123(R) and SEC Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment. Prior to 2005, the Company determined the expected volatility by relying exclusively on the Company s historical stock price changes (using daily pricing).

The Company has never paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. Therefore, the Company used an expected dividend yield of zero in the Black-Scholes-Merton option-pricing model.

The expected term of stock options granted represents the period of time that they are expected to be outstanding. Historically, the Company determined the expected term of stock options based on either Section 16 insider reported data from a select group of peer companies (in 2005) or a period that was equivalent to the vesting period (in 2004). In May 2006, the Company s stockholders approved an amendment and restatement of The 2003 Incentive Award Plan that decreased the maximum contractual term of prospective option grants from ten years to seven years. Corresponding with this change, the Company revised its determination of the expected term of options by applying a weighted-average calculation combining the average life of options that have already been exercised with the estimated life of all unexercised options.

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 s stock-based compensation expense is based on awards ultimately expected to vest. In 2006, the Company reduced stock-based compensation expense to allow for estimated forfeitures based on historical experience. In the Company s pro forma information required under SFAS No. 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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):

Awards	Weighted Average Remaining Expense Life (Years)		Unrecognized Expense as of December 31, 2006
Options	1.7	$	36,082
ESPP	0.2		86
Restricted Stock	1.7		8,212
Deferred Issuance Restricted Stock	1.4		1,802
		$	46,182

At December 31, 2006, the Company had 238,336 unvested restricted stock and Deferred Issuance Restricted Stock Awards that had a weighted average grant date fair value of $46.45 per share. The fair value of the 44,292 restricted stock and deferred issuance restricted stock awards that vested during 2006 was approximately $1,825,000.

Impact of the adoption of SFAS No. 123(R)

The following table summarizes the stock-based compensation expense for stock option grants and ESPP shares that the Company recorded in its 2006 statement of income in accordance with SFAS No. 123(R) (in thousands, except per share data):

		Year Ended December 31, 2006
Cost of product sales	$	2,264
Research and development		7,360
Marketing and sales		2,828
General and administrative		8,809
Reduction of operating income before income taxes		21,261
Income tax benefit		(7,636)
Reduction of net income	$	13,625
Reduction of net income per share:		
Basic	$	0.26

Diluted	$	0.26

Of the $21,261,000 in stock-based compensation recognized during 2006 related to stock options and employee stock purchases under the ESPP pursuant to the adoption of SFAS No. 123(R), approximately $16,681,000 was related to awards granted prior to January 1, 2006 and $4,580,000 was related to awards granted during 2006. The carrying value of inventories on the Company s balance sheet as of December 31, 2006 includes capitalized employee stock-based compensation costs of $1,161,000. Additionally, in each of May 2006, May 2005 and June 2004, the Company granted to its chief executive officer 20,000 shares of Deferred Issuance Restricted Stock Awards at the fair market value of these awards on the dates of grant. The total fair values of approximately $1,054,000, $871,000 and $839,000, respectively, are being amortized to expense on a straight-line basis over the vesting periods (48 months). For the years ended December 31, 2006, 2005 and 2004, stock-based compensation expense related to restricted stock grants and Deferred Issuance Restricted Stock Awards was $2,462,000,

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

$920,000, and $1,142,000, respectively, which prior to 2006 was recorded under Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees.

Prior to the adoption of SFAS No. 123(R), the Company presented deferred compensation related to shares of deferred issuance restricted stock and shares of restricted stock as a separate component of stockholders equity. On January 1, 2006, in accordance with the provisions of SFAS No. 123(R), the Company reversed the $5,951,000 balance in deferred compensation as an offset against paid-in capital on its balance sheets.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits for deductions resulting from the exercise of stock options as operating activities on its statements of cash flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits for tax deductions in excess of the compensation expense recorded for those options (excess tax benefits) to be classified as financing activities.

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 recorded its estimated compensation expense for employee stock options based upon their intrinsic value on the date of grant pursuant to 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).

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 were as follows (in thousands, except per share data):

	Years Ended December 31,	
	2005	2004
Net income:		
As reported	$ 60,089	$ 54,575
Stock-based employee compensation expense included in reported net income, net of related tax effects	470	601
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(15,309)	(13,280)
Pro forma net income	$ 45,250	$ 41,896
Net income per share:		
As reported		
Basic	$ 1.19	$ 1.10
Diluted	$ 1.15	$ 1.06

Pro forma		
Basic	$ 0.89	$ 0.85
Diluted	$ 0.86	$ 0.82

Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share, SFAS No. 123(R). Basic net income per share is computed by dividing the net income for the period by the weighted

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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):

	December 31		
	2006	2005	2004
Net income	$ 59,498	$ 60,089	$ 54,575
Weighted average shares outstanding Basic	51,538	50,617	49,429
Effect of dilutive common stock options outstanding	1,563	1,828	1,974
Weighted average shares outstanding Diluted	53,101	52,445	51,403
Net income per share:			
Basic	$ 1.15	$ 1.19	$ 1.10
Diluted	$ 1.12	$ 1.15	$ 1.06

Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 1,338,788, 210,995 and 244,296 for the years ended December 31, 2006, 2005 and 2004, 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 records product sales from the manufacture and shipment of tests for screening donated blood that have received governmental approvals at contractual transfer prices specified in its agreement with its third-party collaboration partner, Novartis Vaccines and Diagnostics, Inc. (Novartis). Blood screening product sales are then adjusted monthly corresponding to Novartis payment of amounts reflecting the Company s ultimate share of net revenue from sales by Novartis to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Novartis to third parties, less freight, duty and certain other adjustments specified in the Company s collaboration agreement with Novartis, as amended, multiplied by the Company s share of the net revenue. The collaboration agreement, as amended, does not allow for any adjustments downward to the transfer price; therefore, the associated transfer price revenues will never be overstated. The Company s share of net revenues from commercial sales of assays that include a test for Hepatitus C Virus (HCV) or West Nile Virus (WNV) is 45.75% or 50.0%, respectively. Based on the terms of the Company s collaboration agreement with Novartis, as amended, the Company s ultimate share of the net revenue from sales to the end user is not known until reported by Novartis.

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.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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.

Royalty revenue is recognized related to the manufacture, 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.

Cost of revenues

Cost of product sales reflects the costs applicable to products shipped for which product sales revenue is recognized in accordance with the Company s revenue recognition policy. The Company manufactures products for commercial sale as well as development stage products for internal use or clinical evaluation. The Company follows SFAS No. 2, Accounting for Research and Development Costs in classifying costs between cost of product sales and research and development costs.

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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.

Shipping and handling expenses

Shipping and handling expenses are included in cost of product sales and totaled approximately $4,951,000, $4,280,000, and $2,569,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Contingencies

Contingent gains are not recorded in the Company s 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 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 (first-in, first-out) or market. 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 (G&A) expenses.

Capitalized software costs

The Company capitalizes costs incurred in the development of computer software related products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product of 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 $21,190,000, $16,265,000 and $14,497,000 for the years ended December 31, 2006, 2005 and 2004, 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

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

estimated useful lives. See Note 4 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 intangibles over the remaining economic life of the relevant technology, which currently ranges from 1.5 to 19.9 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 2006 and determined that no impairment loss was necessary. If the assets were considered to be impaired, the impairment charge would be the amount by which the carrying value of the assets exceeds the fair value of the assets.

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, periodically and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, the Company performs an impairment analysis to determine if it expects to recover the costs through the subsequent sales of applicable products. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2006.

Self-insurance reserves

The Company s consolidated balance sheets at December 31, 2006 and 2005 include approximately $1,698,000 and $1,816,000, 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 (loss) income

In accordance with SFAS No. 130, Reporting Comprehensive Income, all components of comprehensive income, including net income, are reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

circumstances from non-owner sources. Net income and other comprehensive (loss) income, 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 expensed as incurred in accordance with SFAS No. 2.

Income taxes

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.

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year presentation.

New accounting requirements

Adoption of SAB No. 108

In September 2006, the SEC released Staff Accounting Bulleting No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, (SAB No. 108). SAB No. 108, which is effective for fiscal years ending after November 15, 2006, provides guidance on how the effects of prior year uncorrected misstatements, previously deemed to be immaterial, must be considered and adjusted during the current year.

In SAB No. 108, the SEC acknowledged that diversity existed in how to accumulate and quantify misstatements, and provided companies new guidance in this area. SAB No. 108 requires companies to assess the effects of uncorrected misstatements using each of two methods. The first method, known as the rollover method, quantifies a misstatement based on the effect of correcting the misstatement that exists in the current year statement of income. SAB No. 108 also requires companies to assess the materiality of correcting the misstatement using a technique known as the iron

curtain method. The iron curtain method quantifies a misstatement existing in the balance sheet based on the effects of correcting it, on a cumulative basis, at the end of the current year, regardless of in which year the misstatement originated. In addition, SAB No. 108 requires companies to use the iron curtain method to evaluate the materiality of the cumulative misstatement to prior years statements of income.

If a misstatement made in a prior year is deemed immaterial under a company s historical assessment approach, but is deemed material under the additional method, the newly instituted SAB No. 108 allows companies,

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GEN-PROBE INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

in the year of adopting the standard, to correct the misstatement by adjusting the opening balance of stockholders equity. SAB No. 108 also requires the adjustment of any prior quarterly financial statements in SEC filings within the fiscal year of adoption for the effects of such misstatements. This adjustment does not require reports previously filed with the SEC to be amended.

Historically, the Company has assessed all misstatements under the rollover method. In applying this new standard, the Company was required to review any uncorrected misstatements relating to its 2004 and 2005 financial statements. As a result of this review, one misstatement that the Company previously concluded was not material, under the rollover method, was determined to be material under the iron curtain method. This misstatement is described below.

In March 2003, the Company completed an analysis of the appropriate levels of labor and overhead to be included in its costs of inventories. As a result of this analysis, the Company concluded that inventories had been understated, and cost of product sales therefore overstated, by approximately $11,400,000 over a period of several years, primarily due to the substantial growth of its manufacturing operations. More specifically, the analysis concluded that costs such as quality control and manufacturing equipment support, which historically had been included in cost of product sales as a period expense, should have first been capitalized into inventories. Rather than recording the re-valuation of inventories as a one-time benefit to its statement of income in 2003, which would have materially overstated net income, the Company chose to amortize the increase in the value of inventories over six years. To correct the under-valuation of inventories in this manner, the Company increased the value of inventories and established a revaluation reserve equal to the increase in the value of the inventories. The six-year amortization period was chosen because the under-valuation of inventories had accumulated over many years, because some of the inventories involved had a long economic life, and to ensure that increasing the value of inventories would not materially affect earnings in any future reporting period. As a result of utilizing this approach, the Company was amortizing the inventories revaluation reserve, as a reduction to its cost of product sales, by up to $1,990,000 each year beginning in 2003. The impact on its financial statements for 2004 and 2005 was not material, when assessed under the rollover method. As required under the iron curtain method, the Company reassessed the materiality of the unamortized balance as of December 31, 2005 on its 2005 reported financial statements, as if the entire reserve on the balance sheet, $6,466,000, was corrected through the 2005 statement of income. As a result of utilizing the iron curtain methodology of correcting the under-valuation of inventories, the Company concluded that the effect would be material.

In accordance with the transition guidance provided by SAB No. 108, the Company adjusted its January 1, 2006 retained earnings by the net impact of the under-valuation of inventories, which was $3,883,000. Further, the Company recorded an adjustment to increase its January 1, 2006 balances of inventories by $6,466,000 and its tax accounts by $2,583,000. The Company also recast its financial results for the first three quarters of 2006, to reverse a

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total of $1,492,000 of the amortization of the revaluation reserve, as shown in the table below (in thousands, except per share data):

	Three Months Ended			Nine Months Ended	Six Months Ended
	September 30, 2006	June 30, 2006	March 31, 2006	September 30, 2006	June 30, 2006
As reported:					
Cost of product sales	$ 23,801	$ 24,802	$ 26,112	$ 74,715	$ 50,914
Income tax expense	8,779	8,021	8,523	25,323	16,544
Net income	15,116	13,630	14,532	43,278	28,162
Net income per share Basic	$ 0.29	$ 0.26	$ 0.28	$ 0.84	$ 0.55
Diluted	$ 0.28	$ 0.26	$ 0.27	$ 0.82	$ 0.53
Adjustment:					
Cost of product sales	$ 497	$ 498	$ 497	$ 1,492	$ 995
Income tax expense	(192)	(193)	(193)	(578)	(386)
Net income	(305)	(305)	(304)	(914)	(609)
Percent of reported net income	2.0%	2.2%	2.1%	2.1%	2.2%
Net income per share Basic	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.01)
Diluted	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.01)
As adjusted:					
Cost of product sales	$ 24,298	$ 25,300	$ 26,609	$ 76,207	$ 51,909
Income tax expense	8,587	7,828	8,330	24,745	16,158
Net income	14,811	13,325	14,228	42,364	27,553
Net income per share Basic	$ 0.29	$ 0.26	$ 0.28	$ 0.82	$ 0.54
Diluted	$ 0.28	$ 0.25	$ 0.27	$ 0.80	$ 0.52
Weighted average shares outstanding, as reported:					
Basic	51,638	51,563	51,248	51,407	51,403
Diluted	53,180	53,186	52,865	53,001	53,023

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Had the re-valuation of inventories been recorded as a benefit to the statements of income in cost of product sales prior to 2003, the Company s financial results would have been adjusted as follows (in thousands, except per share data):

	Years Ended December 31,		
	2005	2004	2003
As reported:			
Cost of product sales	$ 83,900	$ 59,908	$ 45,458
Income tax expense	31,605	30,004	19,766
Net income	60,089	54,575	35,330
Net income per share			
Basic	$ 1.19	$ 1.10	$ 0.74
Diluted	$ 1.15	$ 1.06	$ 0.72
Adjustment:			
Cost of product sales	$ 1,990	$ 1,990	$ 957
Income tax expense	(805)	(806)	(388)
Net income	(1,185)	(1,184)	(569)
Percent of reported net income	2.0%	2.2%	1.6%
Net income per share			
Basic	$ (0.02)	$ (0.02)	$ (0.01)
Diluted	$ (0.02)	$ (0.02)	$ (0.01)
As adjusted:			
Cost of product sales	$ 85,890	$ 61,898	$ 46,415
Income tax expense	30,800	29,198	19,378
Net income	58,904	53,391	34,761
Net income per share			
Basic	$ 1.16	$ 1.08	$ 0.72
Diluted	$ 1.12	$ 1.04	$ 0.71

Future accounting requirements

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN No. 48) Accounting for Uncertainty in Income Taxes an interpretation of SFAS No. 109, 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 is evaluating whether the adoption of FIN No. 48 will have a material effect on its statements of income. The Company does not anticipate the adoption of FIN No. 48 will have a material effect on its statements of income and effective tax rate in future periods.

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2. Balance sheet information

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

Inventories

	December 31	
	2006	2005
Raw materials and supplies	$ 9,479	$ 5,430
Work in process	25,018	17,934
Finished goods	17,559	12,978
	$ 52,056	$ 36,342

Property, plant and equipment

	December 31	
	2006	2005
Land	$ 13,862	$ 9,100
Building	70,928	39,535
Machinery and equipment	128,572	106,433
Leasehold improvements	28,185	16,301
Furniture and fixtures	15,995	10,346
Construction in-progress	618	32,143
Property, plant and equipment (at cost)	258,160	213,858
Less accumulated depreciation and amortization	(123,546)	(108,668)
Property, plant and equipment (net)	$ 134,614	$ 105,190

3. Short-term investments

The following is a summary of short-term investments as of December 31, 2006 (in thousands):

	Gross Unrealized	Gross Unrealized	Estimated