GEN PROBE INC
Form 10-K
March 13, 2006

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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, 2005

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**
None	None

Securities to be registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.0001 per share

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, 2005, 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 $1.5 billion, based on the closing price of the registrant s common stock on the Nasdaq National 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. This determination of affiliate status for purposes of this calculation is not necessarily a conclusive determination for other purposes.

As of March 1, 2006, 51,387,882 shares of registrant s common stock, $0.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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PART I

TRADEMARKS AND TRADE NAMES

ACCUPROBE®, 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 Chiron Corporation. VERSANT® is a trademark 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, pro forma similar words (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

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diagnostic products in the 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 our FDA-approved human immunodeficiency virus (type 1), or HIV-1, assay, hepatitis C virus, or HCV, assay, and Procleix West Nile virus, or WNV, assay are currently utilized to screen over 80% of the United States donated blood supply for HIV-1, HCV and WNV. In addition, we believe our TIGRIS instrument is the only integrated, fully-automated, high-throughput instrument approved for NAT testing in clinical diagnostic applications by the FDA. The TIGRIS instrument is also currently used for investigational use in blood screening applications in the United States and has been approved for use in Europe with our Procleix Ultrio assay. We have more than 20 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, by President George W. Bush 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 and Canada through our direct sales and service force of approximately 57 representatives. Our blood screening products are marketed and distributed worldwide by Chiron Corporation, or Chiron. In addition, we have agreements with Bayer Corporation, bioMérieux, Inc. and Fujirebio, through its subsidiary Rebio Gen, Inc., to market some of our products in various global markets. We are currently involved in arbitration proceedings with Bayer regarding its distribution rights under our collaboration agreement. In addition to product sales, we also generate revenues through research collaborations with government organizations and healthcare 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, water, industrial processes and pharmaceutical and beverage manufacturing processes. We have entered into collaboration agreements with GE Infrastructure Water and Process Technologies, or GEI, a unit of General Electric Company, and Millipore Corporation, or Millipore, under which we will be primarily responsible for developing and manufacturing assays for exclusive use or sale by our collaborative partners in specified fields within the industrial testing market.

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 to perform our assays.

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 approval 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. 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 Chiron. We have also developed the Procleix Ultrio assay, in collaboration with Chiron, which adds an assay 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 semi-automated

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instrument, received its Conformite Europeene, or CE, mark, which permitted Chiron to launch the product in the European Economic Area. The TIGRIS instrument, and our Procleix Ultrio assay for use on the TIGRIS instrument, received CE marks in December 2004, which permitted Chiron to begin commercialization of the Procleix TIGRIS instrument in the European Economic Area.

In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared enhanced semi-automated instrument system, or eSAS, for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. Also in October 2005, we received a complete review letter from the FDA setting forth questions regarding our Biologics License Application, or BLA, for the Procleix Ultrio assay itself. We anticipate submitting a BLA amendment for the Procleix Ultrio assay for use on eSAS, responding to the FDA s questions, by the end of the first quarter of 2006. We anticipate submitting a new 510(k) application for the TIGRIS instrument for use with the Procleix Ultrio assay following clearance of the TIGRIS instrument for use with the WNV assay. We anticipate submitting a (post-approval) BLA supplement for the Procleix Ultrio assay, for use on the TIGRIS instrument, following approval of the BLA for the Procleix Ultrio assay on eSAS. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

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. We intend to submit for 510(k) clearance of the TIGRIS instrument for use with the WNV assay in the first part of 2006. We plan to submit a (post-approval) supplement to our WNV assay BLA, adding the TIGRIS instrument, at approximately the same time.

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 National 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.

Technology

Nucleic acid testing technology is based on detection of unique portions of nucleic acids, which store and transfer genetic information in all 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 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.

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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 allows a scientist to use 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 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. In addition, without amplified NAT, more invasive methods of collection like cervical or urethral swabs must be used.

According to Boston Biomedical Consultants, Inc., the worldwide in vitro diagnostic, or IVD, NAT market was approximately $2.1 billion in 2005. While NAT represents only a small portion of the estimated $30 billion worldwide IVD market, it is one of the fastest growing segments. Boston Biomedical Consultants, Inc. reported that the worldwide NAT market grew approximately 10% from 2004 to 2005. We focus our business on market opportunities in three segments of the NAT market, clinical diagnostics, blood screening and industrial testing. The clinical diagnostic market has historically accounted for the majority of our NAT

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sales. According to Sannes and Associates, Inc., our products represented approximately 51% of the total chlamydia and gonorrhea tests sold in the United States in 2005. In blood screening, we estimate that our Procleix HIV-1/ HCV assay and WNV assay are currently utilized to screen over 80% of the United States donated blood supply for HIV-1, HCV and WNV. In order to address the emerging NAT market for industrial testing, in July 2005, we entered into a collaboration agreement with GEI to develop, manufacture and commercialize NAT products designed to detect the unique genetic sequences of microorganisms for GEI s exclusive use or sale in selected water testing applications. In August 2005, we entered into a collaboration agreement with Millipore to develop, manufacture and commercialize NAT products for rapid microbiological and viral monitoring for Millipore s exclusive use or sale in process monitoring in the biotechnology and pharmaceutical manufacturing industries. The diagram below illustrates existing and emerging worldwide NAT markets with some examples of product targets of Gen-Probe and 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 condition of infection with the bacterium *Chlamydia trachomatis*, is the most prevalent bacterial sexually transmitted infection in the United States, with an estimated

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2.8 million new cases in the United States each year according to the Centers for Disease Control, or CDC. The clinical consequences of undiagnosed and untreated chlamydia infections include pelvic inflammatory disease, ectopic pregnancy and infertility. Gonorrhea, the disease caused by the bacterium *Neisseria gonorrhoeae*, is the second most frequently reported bacterial STD in the United States, according to the CDC. The CDC estimates that each year approximately 700,000 people in the United States develop gonorrhea. Untreated gonorrhea is also a major cause of pelvic inflammatory disease, which may lead to infertility or abnormal pregnancies. In addition, recent data suggest that gonorrhea facilitates HIV transmission. Chlamydia and gonorrhea infections frequently co-exist, complicating the clinical differential diagnosis. Because chlamydia and gonorrhea infections are often asymptomatic, screening programs are important in high-risk populations such as sexually active men and women between the ages of 15 and 25.

Tuberculosis, or TB, the disease caused by the microorganism *Mycobacterium tuberculosis*, remains one of the deadliest diseases in the world. Group B Streptococcus, or GBS, represents a major infectious cause of illness and death in newborns in the United States and can cause epilepsy, cerebral palsy, visual impairment, permanent brain damage and retardation. Group A Streptococcus, or GAS, is the cause of strep throat, which if left untreated may cause serious complications, such as rheumatic fever and rheumatic heart disease.

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 WHO, about 80% of newly infected patients progress to develop chronic infection, which can lead to both cirrhosis and liver cancer. WHO reports that approximately 170 million people are infected worldwide with HCV. According to the CDC, an estimated 3.9 million people in the United States have been infected with HCV, of whom 2.7 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.

Blood Screening. The field of blood screening has been one of the fastest growing areas for NAT assays. According to the World Health Organization, or WHO, each year more than 75 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 individual units 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 units individually rather than in pools.

Prior to the introduction of NAT for blood screening, blood collection centers primarily used immunoassays to determine the presence of blood-borne pathogens through the detection of virus-specific antibodies and viral antigens. These tests either directly detect the viral antigens or detect antibodies formed by the body in response to the virus. However, this response may take some time. Consequently, if the donor has not developed detectable antibodies or detectable amounts of viral antigens as of the time of the donation, recipients of that blood may be unwittingly exposed to serious disease. In the case of HIV-1, antibodies are detectable in the blood approximately 22 days after infection. With HCV, the window between the time of infection and the detection of the antibodies is much longer, approximately 70 days or more. NAT technology can narrow both windows significantly through amplification and detection of the nucleic acid material of the

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viruses themselves rather than requiring the development of detectable levels of antibodies or viral antigens. According to the CDC, NAT will reduce 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, for IDT.

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. It is becoming increasingly difficult for clinical laboratories to recruit and retain skilled laboratory technologists. Within the STD segment, we anticipate that demand for automated testing will increase as the technology is applied to diagnose new target microorganisms, including human papillomavirus, or HPV, which has been linked to cervical cancer, and the herpes simplex virus. The rate of market growth for testing additional STD-related 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 individual donor testing 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 and 2005, various blood collection centers used our technology and assays, under an investigational exemption, for individual donor testing. Approximately 1,500 infected units have been intercepted using our WNV assay since June 2003.

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. 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. In addition, we have recently entered into a research agreement with SmithKline Beecham Corporation, doing business as GlaxoSmithKline, and SmithKline Beecham (Cork) Ltd., together referred to as GSK, and a research agreement with the Henry M. Jackson Foundation and the Uniformed Services University of Health Sciences, that together operate the Center for Prostate Disease Research, which we believe will provide us with opportunities to further assess our cancer diagnostic portfolio. We have also licensed innovative cell capture technology from AdnaGen AG that may allow for improved isolation of prostate cancer cells.

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 environmental and industrial water testing for harmful bacteria. We believe the move to rapid molecular methods is being driven by economic factors as

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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 and Millipore 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 believe that NAT diagnostic 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. NAT-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 biopharmaceutical processes and environmental and industrial water testing, emerging non-clinical markets for NAT include food, beverage, 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. The majority of 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, on January 23, 2006, Abbott Laboratories announced it had received CE mark certification for 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 announced CE mark certification for its real-time COBAS AmpliPrep/ COBAS TaqMan tests for HIV-1, HCV, and HBV. We intend to develop assays for our collaborations with GEI and Millipore using real-time technology.

Our Competitive Strengths

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

Proprietary Core Technologies

We believe that we have developed one of the broadest portfolios of NAT technologies in the industry. Our products incorporate these technologies, which, in combination, have significantly advanced our NAT assays, making them more specific, more sensitive, easier to use and faster to result than products based on competing NAT technologies. For example, our proprietary Transcription-Mediated Amplification, or TMA, technology offers 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

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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 granted us marketing approval to use our WNV assay to screen donated human blood on eSAS. Our NAT assays currently are performed on our proprietary luminometers and our semi-automated Direct Tube Sampling, or DTS, and TIGRIS (in the case of our APTIMA Combo 2 and Procleix Ultrio assays) instruments. As of December 31, 2005, we had more than 390 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, 2005, our world-class research and development group consisted of 230 full-time employees, 108 of whom hold advanced degrees. From our PACE family of products to our amplified APTIMA Combo 2 assay, which can 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 NAT clinical diagnostics and blood screening. To complement these products, we have developed and continue to develop 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 2005 were to repeat customers. We believe that our brand name also facilitates market acceptance of our new products, providing us with opportunities for growth. Based on information we receive from Chiron, we believe that since 1998 the American Red Cross has used us as its sole source for NAT assays for blood screening, which we believe exemplifies our standing in the industry.

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Sales and Technical Support Capabilities

As of December 31, 2005, our direct sales force consisted of approximately 41 representatives and a 16-member technical field support group. 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 eight 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, Clinical 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 over 100 regulatory, clinical and quality systems professionals has successfully led us through multiple quality and compliance 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 global leader in independent testing and assessment services. We believe our expertise in regulatory, clinical 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 rigorous standards set by governing bodies and our customers.

Our Growth Strategy

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

Establish Leadership Positions in New Markets by Leveraging Our Core Technologies

We have had a successful track record in identifying new product and market opportunities and becoming the market leader in a number of NAT testing segments by providing innovative product solutions based on our proprietary technology base. In the past, we have utilized our patented technology portfolio, innovation and market development expertise to establish leadership positions in areas such as chlamydia and gonorrhea testing. Our ability to strategically identify and assume leadership roles in new markets was evidenced by our entrance into the blood screening market. We successfully developed the first FDA-approved NAT assay for HIV-1/ HCV detection, our Procleix HIV-1/ HCV assay, which we estimate is currently used to screen over 80% of the United States donated blood supply. Our WNV assay, which received FDA marketing approval in December 2005 for screening donated human blood on eSAS, also is currently being used to screen more than an estimated 80% of the United States blood supply. We received CE mark clearance for the use of the Procleix Ultrio assay in conjunction with our TIGRIS instrument for Europe, which represents the first fully automated blood screening NAT system cleared for commercial distribution in Europe.

We currently 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. 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. 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

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biotechnology and pharmaceutical manufacturing industries. We also are evaluating product opportunities in genetics, pharmacogenomics, food and environmental testing.

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 STD testing on the TIGRIS instrument. The TIGRIS instrument should significantly reduce the time, labor costs, risk of contamination and complexity associated with performing NAT assays and blood screening. We believe that the increased utility of this platform will lead to significant advances in both the clinical diagnostics and blood screening markets. The automation and increased throughput of the TIGRIS instrument will enable 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 penetrate new markets.

Expand Our Menu of NAT Probe Assays through Innovative Research and Development

We intend to continue to 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 Chiron, 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 immunodiagnostic tests. 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 available to be performed on the instruments we place with our customers.

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, ovarian, kidney, lung, colon 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.

Expand 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 Chiron for the blood screening market has allowed us to combine our NAT technology with

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Chiron s patent portfolio relating to HIV and HCV and to leverage Chiron s distribution and sales resources. Further, we believe our collaborations with GEI and Millipore, pursuant to which each will manage worldwide commercialization of any products resulting from the respective collaborations, will enable us to access their large customer bases in the markets for industrial water testing and biopharmaceutical processes 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, making 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 organisms 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 single-copy 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.

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

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support, which allows the support, with the target bound to it, to be removed 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 instablility 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 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. Many 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 produces 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 give increased fluorescent outputs with increasing amounts of amplified target nucleic acid. In these assay formats, amplification and detection take place simultaneously. Consequently, the total time to get 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 DKA 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 modern 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 categorize our products into clinical diagnostic products and blood screening products.

Clinical Diagnostic Products.

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

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Clinical Diagnostic Products for the Detection of Non-Viral Microorganisms. We have developed FDA-approved amplified and non-amplified NAT assays that detect non-viral microorganisms primarily for use in clinical diagnostics. We have established a market-leading position in non-amplified NAT assays, particularly with respect to assays for the detection of chlamydia and gonorrhea, and we have obtained FDA approval for an amplified STD test to compete in that market segment. Our principal products for the detection of non-viral microorganisms include our non-amplified AccuProbe and non-amplified PACE family of products and our amplified Mycobacterium Tuberculosis Direct Test and amplified APTIMA Combo 2 product, 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	Gen-Probe North America bioMérieux,

			October 1994	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

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Product Line	Principal Technologies	Target Microorganism	FDA Clearance/Approval	Commercial Distribution
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
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 and detection by Dual Kinetic Assay	*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 NAT assays have proven to be more sensitive and specific than traditional enzyme immunoassay methods. 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 today s 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 accounted for 16% of our total revenues in 2005, 20% of our total revenues in 2004 and 29% of our total revenues in 2003. The decrease in the percentage of total revenues represented by our PACE family of assays is attributable to two factors. First, our total revenues

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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 converting 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, often resulting in a patient not receiving appropriate treatment on a timely basis or receiving unnecessary treatment. 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 assay was the first amplified NAT assay for obtaining same day results from sputum samples.

APTIMA Combo 2. To meet market demand for amplified STD assays, we developed our APTIMA Combo 2 assay, which received FDA approval 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. APTIMA Combo 2 has the sensitivity and specificity to detect chlamydia infections and gonorrhea from both symptomatic and asymptomatic individuals.

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 approval for the APTIMA Vaginal Swab Specimen Collection Kit, the first kit that enables patients to self-collect vaginal swab specimens to be tested for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using the APTIMA Combo 2 assay.

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 infections 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, 80% of which are liquid-based. We anticipate filing for regulatory clearance in the United States of a similar application from TriPath s liquid Pap transport media in 2006.

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. We also have developed ASRs to detect the parasite

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Trichomonas vaginalis that causes the sexually transmitted disease trichomoniasis. Trichomoniasis is one of the most common sexually transmitted diseases 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 in vitro diagnostic reagents to bridge the gap between research and assays that have received FDA approval. The FDA has created a series of regulations governing these reagents. ASRs use a collection of specific reagents that, when combined with general purpose reagents, give clinical diagnostic testing laboratories the ability to build 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 submissions.

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 and an ASR for quantitative HCV testing, as set forth below, and currently are run on our semi-automated instruments incorporating components of our DTS instrument.

Clinical Diagnostic Products for the Detection of Viral Microorganisms

Product Line	Principal Technologies	Target Microorganism	FDA Clearance/Approval	Commercial Distribution
Qualitative HCV Assay	Target Capture, Transcription-Mediated Amplification of viral RNA, detection by Dual Kinetic Assay	HCV	November 2002	Bayer Worldwide
ASR for Quantitative HCV Testing	Target Capture, Transcription-Mediated Amplification of viral RNA, detection by Hybridization Protection Assay	HCV	Not required	Bayer 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, 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. Bayer currently distributes this assay under the trademark VERSANT in the United States and other international markets under our collaboration agreement.

ASR for Quantitative HCV Testing. We also have developed, through our collaboration with Bayer, an ASR to quantitatively determine the amount of HCV present in a sample. This ASR currently is provided by Bayer to Quest Diagnostics Incorporated, a leading national diagnostics company.

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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	February 2002	Chiron Worldwide
Procleix WNV Assay	Target Capture, Transcription- Mediated Amplification of viral RNAs, detection by Dual Kinetic Assay	WNV in donated blood	December 2005	Chiron U.S.
Procleix Ultrio Assay	Target Capture, Transcription- Mediated Amplification of viral RNAs, detection by Dual Kinetic Assay	HIV-1, HCV and HBV in donated blood	Not approved	Chiron Worldwide (except U.S.)

In 1998, in collaboration with Chiron, we were selected by The American Red Cross to provide it with an HIV-1/ HCV assay for testing pooled blood samples under an IND filed with the FDA. The Red Cross is the largest supplier of blood, plasma and tissue products in the United States. The Red Cross provides almost half of the nation s entire blood supply through its 36 region national network. The Gen-Probe/ Chiron 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 assays supplied under the IND were delivered on a cost recovery basis.

The FDA approved our BLA for the Procleix HIV-1/ HCV assay in February 2002. As a result of FDA approval, Chiron 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. The Procleix HIV-1/ HCV assay has received approval in the United States, some European countries, and in Asia. Regulations adopted by the European Union, or EU, required all imported in vitro diagnostic products, including our existing blood screening assays, to be registered and receive CE mark approval 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 separate units and then conducting a probe-based test on the pooled samples. The Procleix 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 blood individually. Because of the unit volume of donated blood, testing all units individually is currently impractical without fully automated instrumentation. Accordingly, we have invested in the development of the TIGRIS instrument, which we believe will provide the automation necessary to facilitate individual donor testing.

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In collaboration with Chiron, 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 Chiron. 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 immunodiagnostic tests. 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 received its CE mark in January 2004. In December 2004, the TIGRIS instrument received a CE mark for use with the previously CE marked Procleix Ultrio assay 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. During the third quarter of 2004, we submitted a BLA to the FDA to permit commercial sales of the Procleix Ultrio assay in the United States. We intend to seek approval in the United States to run the test on both eSAS and on the fully-automated TIGRIS instrument.

In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. Also in October 2005, we received a complete review letter from the FDA setting forth questions regarding our BLA for the Procleix Ultrio assay itself. We anticipate submitting a BLA amendment for the Procleix Ultrio assay for use on eSAS, responding to the FDA s questions, by the end of the first quarter of 2006. We anticipate submitting a new 510(k) application for the TIGRIS instrument for use with the Procleix Ultrio assay following clearance of the TIGRIS instrument for use with the WNV assay. We anticipate submitting a (post-approval) BLA supplement for the Procleix Ultrio assay, for use on the TIGRIS instrument, following approval of the BLA for the Procleix Ultrio assay on eSAS. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

In June 2003, we announced that our WNV assay was available for use by United States blood collection centers under an IND application to begin clinical testing of the virus in freshly donated human blood. 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. As of December 2005, blood collection centers in the United States had used the WNV assay to screen more than 29 million units of donated blood under the IND application. This testing has resulted in the interception of approximately 1,500 WNV-infected blood donations. 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. We intend to submit for 510(k) clearance of the TIGRIS instrument for use with the WNV assay in the first part of 2006. We plan to submit a (post-approval) supplement to our WNV assay BLA, adding the TIGRIS instrument, at approximately the same time.

Emerging Diagnostic Applications

We entered into a license and collaboration agreement with DiagnoCure to apply our NAT technology in the detection of a new, highly specific genetic marker for prostate cancer. In addition, 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 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

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microbiological and viral monitoring for Millipore s exclusive use or sale in process monitoring in the biotechnology and pharmaceutical manufacturing industries. We are currently evaluating additional product opportunities in other areas of the industrial testing market.

Instrumentation

We have developed and continue to develop instrumentation and software that are 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 set forth in them. By placing our proprietary instrumentation in laboratories and hospitals, we can establish a platform for future sales of our assays. We record the revenue associated with the delivery of our proprietary integrated instrument platforms to customers in product sales. The costs associated with the instrument are charged to cost of sales on a straight-line basis over the estimated life of the instrument, which ranges from three to five years. The costs to maintain these instruments in the field are charged to cost of product sales as incurred. For instruments that will be used for blood screening or in connection with our clinical diagnostic collaboration with Bayer, we sell the instrumentation to Chiron and Bayer, and they are responsible for the placement, maintenance and repair of the units with their laboratory and hospital customers.

Luminometers

We first introduced the LEADER series of luminometers, designed in conjunction with MGM Instruments, Inc., for use with our PACE and AccuProbe products and, more recently, the APTIMA product line. 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 consisting of 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 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.

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 1600 instruments add the additional capabilities of an automated pipetting station and 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.

Chiron markets a version of the DTS 1600 instruments, also known as eSAS, for use in blood screening under the Procleix trademark. The version of the DTS instruments that Chiron markets has received FDA approval and foreign governmental approval in the countries where our blood screening products are sold.

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Bayer markets systems comprised of components of the DTS instruments for HCV clinical diagnostic assays. The systems that Bayer markets do not require FDA or foreign governmental approval.

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, and 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. We have capitalized $25.1 million of third-party costs that we incurred to develop TIGRIS software after establishing technological feasibility. In 2004, we began to amortize the capitalized software costs associated with the TIGRIS instrument.

Clinical trials for clinical diagnostic testing on the TIGRIS instrument using our APTIMA Combo 2 assay were completed in June 2003 and a 510(k) premarket notification was filed with the FDA in July 2003. In December 2003, we received approval from the FDA for testing for certain STDs on the TIGRIS instrument.

In December 2003, we filed an amended IND with the FDA to initiate clinical trials of the Procleix Ultrio blood screening assay on the TIGRIS instrument. We initiated clinical trials of our Procleix Ultrio assay on the TIGRIS instrument for a blood screening application in January 2004. We submitted a BLA for the Procleix Ultrio assay to the FDA during the third quarter of 2004. We intend to seek approval in the United States to run the test on both eSAS and on the fully automated TIGRIS instrument. The Procleix Ultrio assay received its CE mark in January 2004 for use on eSAS and in December 2004 we received a CE mark for the TIGRIS instrument for use with the Procleix Ultrio assay, enabling us to begin commercialization of the Procleix TIGRIS system in the European Economic Area, as well as in other parts of the world that accept the CE mark. In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. We anticipate submitting a new 510(k) application for the TIGRIS instrument for use with the Procleix Ultrio assay following clearance of the TIGRIS instrument for use with the WNV assay. There can be no assurance that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

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. As of December 31, 2005, our direct sales force consisted of a staff of approximately 41 sales representatives. We also support our sales efforts through a staff of 16 field technical representatives. Our sales representatives have an average of approximately 20 years of overall sales experience, with an average of approximately eight years focused on sales of NAT products. Sales representatives principally focus on large accounts including large reference laboratories, public health laboratories and hospitals throughout North America and generally do not focus on physicians at this time. 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

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properly informed about all areas of our product lines and selling processes. Our blood screening products are marketed and distributed by Chiron.

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 intend to continue targeting 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 for educating existing and potential customers about our assays and contains our entire directory of products, on-line technical materials and links to related medical sites.

Sales Strategy

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

Distribution

We have entered into 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 entered into an agreement for distribution of our microbial non-viral diagnostic products in Japan with Chugai Diagnostics Science, which was acquired by Fujirebio in 2002. Fujirebio renamed the company Rebio Gen, Inc. 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 Bayer and the blood screening products we manufacture under our collaboration agreement with Chiron are marketed and distributed by those companies. We are currently involved in arbitration proceedings with Bayer regarding its distribution rights under the collaboration agreement.

Customers

The primary customers for our clinical diagnostic products include large reference laboratories, public health laboratories and hospitals. Our blood screening collaboration with Chiron accounted for 52% of our total revenues in 2005 and 47% of our total revenues in 2004. Our blood screening collaboration with Chiron is largely dependent on two large customers in the United States, The American Red Cross and America s Blood Centers, but we did not receive any revenues directly from these entities. Chiron was our only customer that accounted for greater than 10% of our total revenues in 2005. 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 2005 and 2004. 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 Chiron Corporation

In June 1998, we entered into a strategic alliance with Chiron 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. The Gen-Probe/ Chiron alliance initially developed and is

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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 document. 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 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 agreement to permanently fix our share at 45.75% of net revenues for assays that include a test for HCV after deduction of appropriate expenses. For commercial assays that do not test for HCV, such as the WNV assay, the agreement remains unchanged, with each party retaining 50% of the net revenues after deduction of appropriate expenses. The amendment also eliminates the possibility of Chiron 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 agreement may be extended by the development of new products under the 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. The agreement can be terminated by a party earlier if the other party materially breaches the 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 system, triggering a $6.5 million contract milestone payment from Chiron that we recorded during the first quarter of 2004. During January 2004, the Procleix Ultrio assay, running on our semi-automated instrument, received its CE mark, which permitted Chiron to launch the product in the European Economic Area. In December 2004, use of the TIGRIS instrument with the previously CE marked Procleix Ultrio assay received a CE mark 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.

From inception through December 31, 2005, we recognized a total of $476.5 million in revenue under this collaboration agreement and had recorded $5.0 million in deferred license revenues as of December 31, 2005.

The collaboration agreement provides that Chiron pay us a $10 million milestone upon FDA approval of the Procleix Ultrio assay on the TIGRIS instrument. We believe that this approval is more likely in 2007 than in 2006. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the Procleix Ultrio assay.

On October 30, 2005, Chiron announced that it entered into a merger agreement with Novartis AG. In the event the merger is consummated, Chiron will become a wholly-owned subsidiary of Novartis. We do not know whether the merger will be consummated or, if consummated, what effect, if any, it will have on our relationship with Chiron.

Agreement with Bayer Corporation

In 1998, following the execution of our agreement with Chiron, Chiron assigned the clinical diagnostic portion of the agreement to Bayer. Under the terms of our collaboration with Bayer, we will develop, manufacture and market with Bayer NAT assays for viral targets and cancer markers in the clinical diagnostic market. Pursuant to the collaboration, we and Bayer initially developed and are manufacturing and marketing quantitative ASRs and qualitative assays for HCV. In the event that any third-party technology is needed to

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continue development under our collaboration agreement with Bayer, costs for obtaining such third-party technology will be allocated between the parties. In addition, either party has the right to separately pursue obtaining rights to cancer markers necessary for the development of NAT assays.

Under the terms of this agreement, Bayer agreed to pay us a combination of transfer prices and royalties on product sales. From inception through December 31, 2005, we recognized a total of $12.0 million in revenue under our collaboration agreement with Bayer, including $1.4 million in revenue during 2005.

The collaboration agreement has an initial term of 10 years from the first commercial sale of a clinical diagnostic assay subject to the agreement, which occurred in the second quarter of 2000. The agreement may be extended by the development of new products under the 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. The agreement can be terminated earlier if a party materially breaches the agreement and does not cure the breach following 90 days notice from the non-breaching party or if a 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 November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by us for the detection of HIV, hepatitis virus and other specified viruses, subject to specific conditions. Our demand for arbitration stated that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. In June 2005, the arbitrator issued an Interim Opinion and Award and determined, among other things, that we are entitled to a co-exclusive right to distribute qualitative Transcription-Mediated Amplification, or TMA, assays to detect HCV and HIV-1 for the remaining term of the agreement. Bayer previously held the exclusive rights to market these products. We will be required to pay running sales royalties to Bayer on sales of the TMA assays for HCV and HIV-1, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as we requested. As a result of a termination of the agreement, we will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within JAMS. There can be no assurances as to the final outcome of the arbitration.

National Institutes of Health Contracts

In October 2002, we received a $1.0 million contract extension from the NIH to develop a NAT assay for the detection of the West Nile virus. The NIH allocated an additional $2.5 million to the contract extension in February 2003.

In November 2003, we received $4.3 million of supplemental contract funding from the NIH. This contract extension supported our pursuit of clinical studies and the submission on January 27, 2005 of our BLA for our nucleic acid test for the detection of WNV in donated human blood.

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. From inception through

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December 31, 2005, we recognized $21.4 million in sales revenue under this distribution agreement, including $3.2 million in sales revenue during 2005. The distribution agreement with Rebio Gen, as amended, currently expires by its terms on March 31, 2006. We are currently discussing an extension of the agreement with Rebio Gen. 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.

Purchase and Supply 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. The agreement terminates upon the expiration of certain 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.

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 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

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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.

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.

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 September 2004, at the same time we entered into the termination agreement, 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 $250,000 for limited non-exclusive, non-transferable, research licenses, without the right to grant sublicenses except to affiliates, and non-exclusive, non-transferable options for licenses to develop diagnostic products for certain disease targets using 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 may acquire rights to develop products for additional targets, if any, by paying us up to an additional $0.9 million, the exact total amount based on the number of additional targets, if any, selected by bioMérieux s affiliates by the end of 2006. 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 (6) 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. We will record revenue based on the total number of targets eventually selected.

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On February 3, 2006, bioMérieux terminated the second of the two August 2000 license agreements. Upon payment of minimum royalties for 2006 in the amount of $500,000, bioMérieux will not have any further obligations under the terminated license. Termination of the second August 2000 license does not affect the September 2004 licenses.

Through December 31, 2005, we recognized a total of $58.0 million in revenue under the agreements, including $7.7 million during 2005.

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, we granted Chugai Diagnostics Science Co., Ltd. a non-exclusive license for Japan in the field of human clinical diagnostics to various of our proprietary technologies, including TMA and HPA technology. All rights and title to any discovery, invention or improvement made by Rebio Gen as a result of access to our patent rights licensed under the agreement belong solely to Rebio Gen. We received a license fee and a royalty payment for sales made prior to the effective date of the agreement and will receive royalty payments from 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, 2005, we have recognized a total of $3.1 million in revenue under this agreement, including $0.3 million in revenue during 2005. 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, 2005, we have recognized a total of $4.3 million in revenue under this agreement, including $0.9 million in revenue during 2005. 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 of 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. 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, 2005, we incurred a total of $4.3 million in expenses under this agreement, including $1.6 million in expenses during 2005. Our obligation to make royalty

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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, 2005, we paid royalties to UWCM totaling $4.6 million, including $1.6 million in 2005. 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. Chiron 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. During the fourth quarter of 2004, we began to amortize our share of the payment to cost of goods sold over the patent s remaining economic life of 135 months.

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, we have worldwide rights to develop, use and market kits in the field of human *in vitro* diagnostics and food 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, 2005, we incurred a total of $1.9 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

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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 expected to detect 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 agreed to pay future fees and contract development payments of up to $7.5 million over the three years following execution of the contract. As of December 31, 2005, approximately $2.0 million remained to be paid to DiagnoCure pursuant to this obligation. 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. The agreement provides that we may lose exclusivity with respect to the licensed PCA3 marker if we fail to diligently develop the collaborative diagnostic test. This agreement expires, on a country-by-country basis, on the expiration of our obligation to pay royalties to DiagnoCure, which obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed patent rights. We may terminate the agreement for any reason following 30 days written notice to DiagnoCure, or following 30 days written notice to DiagnoCure in the event a licensed product fails to produce a certain level of results in any clinical trial.

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. During this period, we are evaluating the feasibility of adapting Qualigen s immunoassay platform to perform NAT using our proprietary technologies. If we exercise this option, we will purchase 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 would be approximately $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. 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

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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 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, an additional $1.6 million in February 2006 and have agreed to pay an additional $1.6 million on January 31, 2007, unless we terminate the agreement prior to that date. Pursuant to the agreement, we also agreed to pay Corixa milestone payments totaling an additional $2.0 million on a product-by-product basis based on the occurrence of certain, regulatory and/or commercial events. We also agreed to pay Corixa additional milestone payments and royalties on net sales of any products developed by us using Corixa s technology. The agreement will expire on the expiration of our obligation to pay royalties to Corixa under the agreement, which obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed patent rights. We may terminate the agreement in our sole discretion upon 30 days prior written notice to Corixa, provided we have made any outstanding payments due under the agreement. Either party may terminate the agreement for cause by written notice to the other party of an uncured material breach by the other party or if the other party is unable to pay its debts or enters into compulsory or voluntary liquidation.

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, 2005, we owned more than 390 issued United States and foreign patents. In addition, our patent portfolio includes pending patent applications in the United States and corresponding international filings in major industrial nations.

United States utility patents issued from applications filed prior to June 8, 1995 have a term of the longer of 20 years from the earliest priority date or 17 years from issue. United States utility patents issued from applications filed on or after June 8, 1995 have a term of 20 years from the earlier of the application filing date or earlier claimed priority date of a regular application. 111 of our current United States utility patents issued from applications filed prior to June 8, 1995. 90 of our United States utility patents issued from applications filed on or after June 8, 1995. We have three 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 July 6, 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 for our proprietary software is protected both as a trade secret and as copyrighted work. Our

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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, Becton Dickinson and Company, and bioMérieux S.A. All of these companies are manufacturers of laboratory-based tests and instruments for the NAT market, and we believe that all 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, potential for 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 Laboratories, Becton Dickinson 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. In markets outside of the United States, other factors, including local distribution systems, complex regulatory environments and differing medical philosophies and product preferences, influence competition as well. 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.

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 Laboratories. In the future, our blood screening products may compete with viral inactivation or reduction technologies and blood substitutes.

Chiron, 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. Chiron has granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron has granted HIV and HCV licenses in the clinical diagnostics field to Bayer Healthcare LLC, which also has the right to grant certain additional HIV and HCV sublicenses in the field to third parties. Chiron has granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux) in the clinical diagnostics field. To the extent that Chiron grants additional licenses in blood screening or Bayer 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.

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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.

In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. We anticipate submitting a new 510(k) application for the TIGRIS instrument for use with the Procleix Ultrio assay following clearance of the TIGRIS instrument for use with the WNV assay. There can be no assurance that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

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.

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After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. In addition to potential product specific post-approval requirements, all devices are subject to:

- the Quality System Regulation, which requires manufacturers to follow comprehensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process,
- labeling regulations,
- the FDA s general prohibition against promoting products for unapproved or off-label uses, and
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur.

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

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

- completion of preclinical laboratory testing,
- submission of an IND, which must become effective before biologic 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.

Our clinical trial programs for blood screening products were developed in conjunction with our primary end users, The American Red Cross and America s Blood Centers. Our BLA for the Procleix HIV-1/ HCV

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assay was approved in February 2002. Clinical trials of the Procleix Ultrio assay were completed in 2004 with submission of a BLA in the third quarter of 2004. On October 26, 2005, we received a complete review letter from the FDA setting forth questions regarding our BLA for the Procleix Ultrio assay. We anticipate submitting a BLA amendment for the Procleix Ultrio assay for use on eSAS, responding to the FDA s questions, by the end of the first quarter of 2006. We anticipate submitting a (post-approval) BLA supplement for the Procleix Ultrio assay, for use on the TIGRIS instrument, following approval of the BLA for the Procleix Ultrio assay on eSAS. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the Procleix Ultrio assay.

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. We intend to submit for 510(k) clearance of the TIGRIS instrument for use with the WNV assay in the first part of 2006. We plan to submit a (post-approval) supplement to our WNV assay BLA, adding the TIGRIS instrument, at approximately the same time.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote biologics, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has broad enforcement authority under the FFDCA, and failure to abide by applicable FDA regulations can result in penalties including the issuance of a warning letter directing the entity to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We and our contract medical product manufacturers are subject to periodic inspection by the FDA and other authorities where applicable, and are required to comply with the applicable FDA current Good Manufacturing Practice regulations. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation, and provide for manufacturing facilities to be inspected by the FDA. Manufacturers of biologics also must comply with the FDA s general biological product standards. These standards 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 foreign marketing authorizations 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.

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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 and provides us with highly flexible and cost effective manufacturing capabilities. 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 and organ transplant testing 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 the 291,000 square-foot building we are constructing 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 agreement with F. Hoffmann-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc. for the manufacture and supply of DNA probes for HPV. We work closely with our suppliers to assure continuity of supply while maintaining high quality and reliability. Although we generally consider and identify alternative suppliers, we do not typically pursue alternative sources due to the strength of our existing supplier relationships.

Quality Systems

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

Our regulatory, quality and government affairs department has successfully led us through multiple quality and compliance audits by the FDA, foreign governments and customers. This department also coordinated an audit by TÜV Rheinland of North America, leading to our European Standard, EN 13485, certification. TÜV Rheinland of North America also certifies our Diagnostic CE marking activities.

Research and Development

As of December 31, 2005, we had 256 full-time and temporary employees in research and development. Our research and development expenses were $71.8 million in 2005, $68.5 million in 2004 and $63.6 million in 2003.

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Employees

As of December 31, 2005, we had 866 full-time employees, of whom 186 hold advanced degrees, 230 were in research and development, 119 were in regulatory, clinical and quality systems, 157 were in sales and marketing, 134 were in general and administrative and 226 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, 2005, we had 84 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 research and development 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 blood screening products and some of our clinical diagnostic products, such as APTIMA Combo 2, have a relatively limited sales history, which limits our ability to project future sales and the sales cycle 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.

We are dependent on Chiron 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 Chiron to distribute our blood screening products and Bayer to distribute some of our viral clinical diagnostic products. Commercial product sales by Chiron accounted for 42% of our total revenues for 2005 and 35% of our total revenues for 2004. Our agreement with Chiron will terminate in 2010 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.

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 Chiron commence arbitration against each other in the future under the collaboration agreement, proceedings could delay or decrease our receipt of revenue from Chiron or otherwise disrupt our collaboration with Chiron, which could cause our revenues to decrease and our stock price to decline.

On October 30, 2005, Chiron announced that it entered into a merger agreement with Novartis AG. In the event the merger is consummated, Chiron will become a wholly-owned subsidiary of Novartis. We do not know whether the merger will be consummated or, if consummated, what effect, if any, it will have on our relationship with Chiron.

Our agreement with 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.

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Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by us for the detection of HIV, hepatitis virus and other specified viruses, subject to specific conditions. Our demand for arbitration stated that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. In June 2005, the arbitrator issued an Interim Opinion and Award and determined, among other things, 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 agreement. Bayer previously held the exclusive rights to market these products. We will be required to pay running sales royalties to Bayer on sales of the TMA assays for HCV and HIV-1, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as we requested. As a result of a termination of the agreement, we will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within JAMS. There can be no assurances as to the final outcome of the arbitration. We are also involved in patent litigation with Bayer.

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. Our distribution agreement with bioMérieux terminates on May 1, 2006, although it may terminate earlier under certain circumstances. The distribution rights revert back to us upon termination. Our distribution agreement with Rebio Gen terminates on March 31, 2006. We have commenced discussions with Rebio Gen regarding renewing the distribution agreement. However, we may not be able to renew the agreement on favorable terms, or at all.

If any of our distribution or marketing agreements is terminated, particularly our agreement with Chiron, 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.

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 Chiron 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 the joint development and marketing of our products. In addition, we expect to rely on our corporate collaborators for the commercialization of some of our 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 pre-clinical or clinical 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, our agreement with Chiron will terminate in 2010 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. Subject to the final outcome of our arbitration with Bayer, the remaining provisions of our Bayer collaboration agreement will terminate in 2010. Both collaboration agreements are 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

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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 Chiron and Bayer, 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 have also committed significant resources to our reliability improvement program. Our Vice President, Product Development is leading this effort as her primary assignment. 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. 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 considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. Also in October 2005, we received a complete review letter from the FDA setting forth questions regarding our BLA for the Procleix Ultrio assay itself. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

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.

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

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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.

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. Our products and operations also are often subject to the rules of industrial standards bodies, such as the International Standards Organization. Complying with these rules and regulations could cause us to incur significant additional expenses, which would harm our operating results.

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 which 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 any or all of our diagnostic products.

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 laboratories, public health laboratories and hospitals. 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 Laboratories, Becton Dickinson 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. In markets outside of the United States, other factors, including local distribution systems, complex regulatory environments and differing medical philosophies and product preferences influence competition as well. 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 us. 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. In addition, we have licensed some of our proprietary technology relating to certain clinical diagnostic and food pathogen applications for use on specific instruments to bioMérieux, and we may license other technologies to potential competitors in the future. As a result, we may in the future compete with bioMérieux and these other licensees for sales of products incorporating our technology. 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. Some of our competitors have developed real time or kinetic nucleic acid assays and semi-automated instrument systems for those assays. Our competitors may be 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 Laboratories with respect to immunoassay products. In the future, our blood screening products also may compete with viral inactivation or reduction technologies and blood substitutes.

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Chiron, 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. Chiron has granted HIV and HCV licenses to Roche Molecular Systems in the blood screening and clinical diagnostics fields. Chiron has granted HIV and HCV licenses in the clinical diagnostics field to Bayer Healthcare LLC, which also has the right to grant certain additional HIV and HCV sublicenses in the field to third parties. Chiron has granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux) in the clinical diagnostics field. To the extent that Chiron grants additional licenses in blood screening or Bayer 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 may decrease upon the implementation of individual donor testing.

We currently receive revenues from the sale of our blood screening assays for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test. However, Chiron sells our blood screening assays to blood collection centers on a per donation basis. We expect the blood screening market ultimately to transition from pooled testing to individual donor testing. A greater number of tests will be required for individual donor testing than are now required for pooled testing. Under our collaboration agreement with Chiron, we bear the cost of manufacturing our blood screening assays. The greater number of tests required for 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 may decrease upon the adoption of individual donor testing. We are not able to predict accurately the extent to which our gross profit margin percentage may be negatively affected as a result of individual donor testing, because we do not know the ultimate selling price that Chiron would charge to the end user if individual donor testing were implemented.

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 Chiron. Our blood screening collaboration with Chiron accounted for 52% of our total revenues for 2005, compared to 47% for 2004. Our blood screening collaboration with Chiron 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. Chiron was our only customer that accounted for greater than 10% of our total revenues for 2005. In addition, Quest Diagnostics Incorporated, 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 2005 and 2004. 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 had more than 390 United States and foreign patents covering our products and technologies as of December 31, 2005, 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,

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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 July 6, 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. Bayer recently initiated patent litigation against us alleging that we are developing real-time diagnostic assays for HIV and HCV that are covered by certain patents without the authorization of the patent owner.

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 strategic 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, competitors may develop products based on technology that is not covered by our patents.

In addition to patent protection, we also rely on copyright and trademark protection, trade secrets, know-how, continuing technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of our trade secrets and proprietary information, we require our employees, consultants, advisors and others to whom we disclose confidential information to execute confidentiality and proprietary information agreements. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, there may not be an adequate corrective remedy available. Furthermore, like many companies in our industry, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their 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, are currently facing, 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.

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Recently, we have been involved in a number of patent disputes with third parties, including Bayer, some of which remain unresolved. Additionally, we hold certain rights in the blood screening and clinical diagnostics fields under Chiron patents covering the detection of HIV. In February 2005, the U.S. Patent and Trademark Office declared two interferences related to Chiron s U.S. Patent No. 6,531,276 (Methods For Detecting Human Immunodeficiency Virus Nucleic Acid) (the 276 patent). The first interference is between Chiron 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 Chiron 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). Chiron is the junior party in both interferences. In February 2005, at about the time the interferences were declared, we received a letter from the Institut Pasteur regarding alleged infringement of Institut Pasteur s European Patent EP 0 178 978 (Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus, or LAV) (978 patent), by the HIV-1 nucleic acid screening assays performed on our Procleix system that is marketed and distributed by Chiron. 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 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, 2005, we had approximately $194.4 million of long-lived assets, including $21.0 million of capitalized software relating to our TIGRIS instrument, goodwill of $18.6 million, a $2.5 million investment in Molecular Profiling Institute, Inc., and $47.1 million of capitalized license and manufacturing fees, patents and purchased intangibles. Additionally, we had $32.3 million of land and building, $4.3 million of leasehold improvements, $35.5 million of construction in-progress and $33.1 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 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.

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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 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 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 recently announced delays in FDA clearance for our TIGRIS instrument for blood screening with the Procleix Ultrio assay and regarding our BLA for the Procleix Ultrio assay itself. 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 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 and pharmaceutical 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 these new industrial testing markets. The process of successfully developing products for application in these potential 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 even if no new products are 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 new 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 expensive than existing methods. We will be reliant on our collaborators and their experience and expertise in addressing customer needs and other requirements 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 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 strategic partners. As a result, we will need to continue to generate significant revenues to maintain profitability. Although we expect our

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research and development expenses as a percentage of revenue to decrease in future periods, we may not be able to generate revenues and may not 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 strategic 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 research and development to successfully develop new technologies and products,

to conduct clinical trials,

to obtain regulatory approval for new products,

to file and prosecute patent applications and defend and assert patents to protect our technologies, including through costly litigation,

to manufacture additional products ourselves or through third parties,

to market different products to different markets, either through building our own sales and distribution capabilities or relying on third parties, and

to acquire new technologies, products or companies.

If we raise funds through the issuance of debt or equity, including through the issuance of debt or equity securities pursuant to our Form S-3 shelf registration statement that we filed on August 29, 2003 with the SEC relating to the possible future sale of up to an aggregate of $150 million of debt or equity securities, 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.

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Further, our business would be harmed if we fail to manage effectively the manufacturing of our products. Because we place orders with our manufacturers based on our forecasts of expected demand for our products, 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, 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.

If we or our contract manufacturers are unable to manufacture our products in sufficient quantities, on a timely basis, at acceptable cost 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 assay pouches containing both liquid reagents and dried pellets 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 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 tests 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

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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. A government-mandated recall, or a voluntary recall by us, could divert managerial and financial resources and potentially harm our reputation with customers. In the past, we have had four voluntary recalls, which, in each case, required us to identify and correct the problem. For example, we experienced a recall in June 2004 as a result of a customer complaint about our Mycobacterium Tuberculosis product suggesting reduced stability of one of our reagents. The problem was identified and corrected and customers were provided with replacement reagent. Our products may be subject to additional recalls in the future. Future recalls could be more difficult and costly to correct, may result in the suspension of sales of our products, and may harm our financial results and our reputation.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 21% of our total revenues for 2005 and 15% of our total revenues for 2004. Sales by Chiron of our blood screening products outside of the United States accounted for 78% of our international revenues for 2005 and 58% of our international revenues for 2004. Chiron 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 Chiron each accounted for 5% of our international sales for 2005 and 10% and 6%, respectively, for 2004.

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 HBV, HAV, and parvo B19, as well as 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. Whenever we seek to enter a new international market, we will 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, if and when implemented, could result in lower gross margin rates, as additional tests would be required to deliver the sample results, unless a corresponding increase in sales pricing structure is implemented. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion may lead to lower gross margin rates.

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

We sell our clinical diagnostic products primarily to large reference laboratories, public health laboratories 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 laboratories 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, laboratories and hospitals likely would purchase separate tests for each disease, rather than products that test for more than one microorganism.

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

Disruptions in the supply of raw materials and consumable goods from our single source suppliers, including the Roche Molecular Biochemicals division of Roche Diagnostics GmbH, 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. For example, our current supplier of certain key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is Roche Molecular Biochemicals, and we have a supply agreement for nucleic acids for human papillomavirus with Roche Molecular Systems, each of which are affiliates of Roche Diagnostics GmbH, one of our primary competitors. 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.

We are dependent on technologies we license, and if we fail to 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. If our license with respect to any of these technologies is terminated for any reason, we will not be able to sell

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products that incorporate the technology. Third parties that license technologies to us also may be acquired by our competitors or may otherwise attempt to terminate or restrict our licenses for their commercial benefit. In addition, 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 third parties who 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.

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, particularly Henry L. Nordhoff, our Chairman, President and Chief Executive Officer, or our inability to identify, attract, retain and integrate additional qualified management personnel, could make it difficult for us to manage our business successfully, attract new customers, retain existing customers and pursue our strategic objectives. Although we have employment agreements with our executive officers, we may be unable to retain our existing management. We do not maintain key person life insurance for any of our executive officers.

Competition for skilled sales, marketing, research, product development, engineering, and technical personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of the services of any 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 and forming collaborations, strategic alliances and joint ventures. Any future acquisitions by us also 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 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 to produce our products 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

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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 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, provisions of Delaware law and our rights plan 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 also adopted a rights plan that could discourage, delay or prevent an acquisition of us under certain circumstances. The rights plan provides for preferred stock purchase rights attached to each share of our common stock, which will cause substantial dilution to a person or group acquiring 15% or more of our stock if the acquisition is not approved by our Board of Directors.

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;

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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.

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.

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. For example, in December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. In April 2005, the SEC approved a vote that effectively 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 APB 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 will negatively impact our earnings. For example, recording a charge for employee stock options under SFAS No. 123, Accounting for Stock-Based Compensation, would have reduced our net income by approximately $15.3 million and $13.3 million for 2005 and 2004, respectively.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have recently 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 that may be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the continued implementation of this new system or any future systems could increase our expenses and adversely affect our ability to report in an

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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 estimated earnings per share are based in part upon a forecast of our weighted average shares outstanding at the time of our estimate. 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 adverse 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 Stock 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***

None.

Item 2. ***Properties***

Our worldwide headquarters are located in our 262,000 square-foot Genetic Center Drive, or GCD, facility located in San Diego, California. We own the GCD facility, the land on which it sits and an adjacent 22-acre parcel. We are building a 291,000 square-foot building on the adjacent 22-acre parcel to support our company-wide growth. This building will be used primarily for research and development, office space, warehousing of finished goods and distribution. Approximately 100,000 square feet of the new building will initially be left vacant and used for future expansion. We anticipate that construction of the additional building will be complete in mid 2006 and the first phase will cost approximately $44.4 million, of which $32.1 million was capitalized to construction in-progress as of December 31, 2005. MLT owns a 23,000 square-foot facility in Cardiff, United Kingdom.

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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
Mira Mesa Facility San Diego, California	29,133 square feet	Lease expires in June 2006 with no renewal options
Wateridge Facility San Diego, California	29,141 square feet	Lease expires in October 2006 with no renewal options
Rehco Facility San Diego, California	20,686 square feet	Lease expires in June 2006 for Suite B, August 2006 for Suite C and August 2009 for Suite D, in each case with no renewal options.

We expect to vacate the Mira Mesa and Wateridge facilities, as well as portions of the Rehco facility, following completion of the new building described above.

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. If any of these matters were resolved in a manner unfavorable to us, our business, financial condition and results of operations would be harmed.

Enzo Biochem, Inc.

In June 1999, the Company was sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that the Company and other defendants have willfully infringed United States patent no. 4,900,659, or the 659 patent, through the manufacture and sale of products for the diagnosis of gonorrhea. On July 27, 2004, the District Court granted summary judgment in favor of the Company and other defendants, and against Enzo, holding that the 659 patent is invalid based on the on-sale doctrine. On September 30, 2005, the United States Court of Appeals for the Federal Circuit affirmed the judgment in the Company s favor. Enzo did not file for rehearing with the Federal Circuit or petition the U.S. Supreme Court for a writ of certiorari within the time allowed. The Company believes that this matter is now concluded.

Bayer Corporation

In November 2002, the Company filed a demand for arbitration against Bayer Corporation, or Bayer, in the Judicial Arbitration & Mediation Services, Inc., or JAMS, office in San Diego, California related to the Company s collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. Under the terms of the June 1998 collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of human immunodeficiency virus (HIV), hepatitis viruses and other specified viruses, subject to certain conditions. Gen-Probe s demand for arbitration stated that Bayer failed to fulfill the conditions required to maintain exclusive distribution rights. The arbitration demand sought confirmation that the agreement grants Gen-Probe, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. In November 2003, Bayer filed a counterclaim for money

damages based on alleged delays in the development of the TIGRIS instrument, alleged delays in the development of certain assays, and other claims. Bayer

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Healthcare LLC was also added as a respondent and counterclaimant. The hearing on the matter began on September 13, 2004 and closing arguments were completed on November 3, 2004.

On April 5, 2005, the arbitrator issued a Tentative Opinion and Award, and requested comments be submitted from the parties related to implementation of the decision. After considering and incorporating some of the parties suggestions, on June 24, 2005, the arbitrator issued an Interim Opinion and Award. The Interim Opinion and Award adopted all substantive rulings of the Tentative Opinion and Award. The arbitrator determined that the Company is entitled to a co-exclusive right to distribute qualitative Transcription-Mediated Amplification (TMA) assays to detect the hepatitis C virus (HCV) and HIV-1 for the remaining term of the agreement. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as the Company requested. As a result of a termination of the agreement, the Company will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Bayer also will be required to reimburse the Company $2.0 million for the Company s legal fees and expenses related to the arbitration proceedings. As discussed in Note 3 Summary of significant accounting policies (Contingencies), the Company will not record any award for reimbursement of legal fees and expenses until the arbitration has been finalized and the cash has been received.

The arbitrator rejected Bayer s multimillion-dollar counterclaim for damages. In the June 2005 Interim Opinion and Award, the arbitrator also concluded that an additional hearing would be required to determine whether a royalty payment would be required as a result of the Company exercising its co-exclusive rights to distribute the qualitative TMA assays for HCV and HIV-1, and, if so, the amount and beneficiary of such royalties. The additional hearing took place on September 14 and 15, 2005. On March 3, 2006, the arbitrator issued his Tentative Award following the additional hearing. The arbitrator concluded that Gen-Probe is licensed under the relevant HIV and HCV patents for qualitative assays during the term of the collaboration agreement and that the Company is not obligated to pay Bayer an initial license fee in connection with the sale of those assays. The arbitrator further concluded that the Company will be required to pay running sales royalties to Bayer on the Company s sales of the qualitative TMA assays for HCV and HIV-1. We believe the royalty rates are generally consistent with rates paid by other licensees of the relevant patents. The March 3, 2006 Tentative Award is subject to revision by the arbitrator following comments by the parties.

The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within JAMS. There can be no assurances as to the final outcome of the arbitration.

A separate patent infringement action that the Company filed in March 2004 against Bayer remains pending in the United States District Court for the Southern District of California. This action alleges that Bayer s bDNA nucleic acid tests for HIV and HCV infringe Gen-Probe s U.S. patent no. 5,955,261, entitled Method for Detecting the Presence of Group-Specific Viral mRNA in a Sample, the 261 patent. Bayer s bDNA tests are not covered by the collaboration agreement between the companies. Bayer has denied the allegations of infringement and alleged that the 261 patent is invalid or unenforceable. On August 10, 2005, the Company subsequently amended its complaint to further allege that Bayer s HIV and HCV bDNA tests also infringe Gen-Probe s U.S. patent no. 5,424,413, entitled Branched Nucleic Acid Probes and Gen-Probe s U.S. patent no. 5,451,503, entitled Method for Use of Branched Nucleic Acid Probes. On August 23, 2005, Gen-Probe filed a second patent infringement action against Bayer, alleging that Bayer s bDNA nucleic acid test for hepatitis B virus (HBV) infringes the 261 patent and further alleging that Bayer s bDNA nucleic acid test for HCV infringes Gen-Probe s U.S. patent no. 5,030,557, entitled Means and Method for Enhancing Nucleic Acid Hybridization Assays.

No trial date has been set for either patent infringement case. There can be no assurances as to the final outcome of the litigation.

On October 4, 2005, Bayer filed a demand for arbitration against the Company with the JAMS office in San Francisco, California related to the Company s collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. At the same time, Bayer filed a civil lawsuit against the Company in Superior Court of Massachusetts for Middlesex County. In both the demand for arbitration and the complaint, Bayer alleges

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that the Company is developing real-time diagnostic assays for HIV and HCV that are covered by certain patents, without the authorization of the patent owner. The subject patents were issued to Chiron Corporation and licensed non-exclusively to Bayer. On October 17, 2005, the Company removed the state court suit to federal court in Boston. On October 21, 2005, Bayer moved to remand the case to the Massachusetts state court. On October 27, 2005, the Company filed a motion to dismiss the case. Both motions are under submission for decision by the court. The Company intends to vigorously defend Bayer s allegations. However, there can be no assurance that these matters will be resolved in the Company s favor.

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

No matters were submitted to a vote of security holders during the quarter ended December 31, 2005.

PART II

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

Our common stock has been traded on The Nasdaq National 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 National Market for the periods indicated.

	High	Low
2004		
First Quarter	$ 39.93	$ 31.40
Second Quarter	$ 47.61	$ 32.80
Third Quarter	$ 45.63	$ 29.40
Fourth Quarter	$ 47.10	$ 31.52

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

As of February 28, 2006, there were approximately 7,271 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.

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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, 2005 and, with respect to our consolidated balance sheets, at December 31, 2005 and 2004 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, 2002 and 2001 and the balance sheet data as of December 31, 2003, 2002, and 2001 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.

	2005	2004	2003	2002	2001
			(In thousands, except per share data)		
Statement of income data for the years ended December 31:					
Revenues:					
Product sales	$ 271,650	$ 222,560	$ 188,645	$ 139,932	$ 104,233
Collaborative research revenue	25,843	27,122	15,402	11,032	20,203
Royalty and license revenue	8,472	20,025	3,144	4,633	5,295
Total revenues	305,965	269,707	207,191	155,597	129,731
Operating expenses:					
Cost of product sales	83,900	59,908	45,458	53,411	38,954
Research and development	71,846	68,482	63,565	47,045	54,915
Marketing and sales	31,145	27,191	22,586	18,199	16,247
General and administrative	32,107	31,628	23,233	20,995	15,564
Total operating expenses	218,998	187,209	154,842	139,650	125,680
Income from operations	86,967	82,498	52,349	15,947	4,051
Net income	$ 60,089	$ 54,575	$ 35,330	$ 13,007	$ 4,617
Net income per share:					
Basic	$ 1.19	$ 1.10	$ 0.74	$ 0.27	$ 0.10
Diluted	$ 1.15	$ 1.06	$ 0.72	$ 0.27	$ 0.10
Weighted average shares outstanding:					
Basic	50,617	49,429	47,974	47,600	47,600
Diluted	52,445	51,403	49,137	47,610	47,606
Balance sheet data as of December 31:					
Cash, cash equivalents and short-term investments	$ 220,288	$ 193,826	$ 156,306	$ 107,960	$ 17,750
Working capital	262,659	234,202	169,000	115,288	29,765
Total assets	510,236	411,082	324,741	258,157	160,347
					12,000

Long-term debt, including current portion					
Stockholders equity	447,373	361,029	270,375	215,578	115,807

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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, pro forma or anticipates, or other similar w their use in 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, 2005, 2004 and 2003 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 over 23 years of nucleic acid detection research and product development experience, and our products, which are based on our patented nucleic acid testing, or NAT, technology, are used daily in clinical laboratories and blood collection centers in countries throughout the world.

We have achieved strong growth in both revenues and earnings due principally to the success of our blood screening products which are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, and hepatitis C virus, or HCV, and hepatitis B virus, or HBV. Under our collaboration agreement with Chiron Corporation, or Chiron, we are responsible for the research, development, regulatory process and manufacturing of our blood screening products, while Chiron is responsible for marketing, sales, distribution and service of those products. Since 2002, we have also experienced strong growth in clinical diagnostics for sexually transmitted diseases, or STDs, due to the success of APTIMA Combo 2.

Recent Events

Financial Results

Product sales for 2005 were $271.7 million, compared to $222.6 million in 2004, an increase of 22%. Product sales in 2005 included approximately $5.4 million due to the recognition of previously deferred revenue related to U.S. blood screening products shipped to Chiron s recently established third party warehouse, whereas in the past, we held such inventory in the virtual warehouse and deferred revenue recognition until products were shipped to Chiron s end-customers. Total revenues for 2005 were $306.0 million, compared to $269.7 million in 2004, an increase of 13%. Net income for the year was $60.1 million ($1.15 per diluted share), compared to $54.6 million ($1.06 per diluted share) in 2004, an increase of 10%. The prior year total revenue and net income included a contract milestone of $6.5 million from Chiron and a license fee of $7.0 million earned in connection with our cross-licensing agreement with Tosoh Corporation, or Tosoh. These amounts added approximately $13.5 million to 2004 revenues and $0.17 to 2004 diluted earnings per share.

Corporate Collaborations

In October 2005, we entered into a non-exclusive collaboration with Molecular Profiling Institute, Inc., a private company, to accelerate market development for our pipeline of cancer diagnostics. Under the terms of

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the agreement, Molecular Profiling has agreed to validate, commercialize and undertake market development activities for up to four of our products, starting with our investigational PCA3 assay, which is intended as an aid in the diagnosis of prostate cancer. In addition, in October 2005, we purchased from Molecular Profiling an aggregate of 1,000,000 shares of Series B Preferred Stock at a purchase price per share of $2.50. We have recorded this $2.5 million investment on a cost basis, and will review the asset for impairment on an ongoing basis.

In August 2005, we entered into a collaboration agreement with Millipore Corporation, or 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.

In July 2005, we entered into a collaboration agreement with GE Infrastructure Water and Process Technologies, or GEI, a unit of General Electric Company, 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.

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 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. Collection of urine samples from selected study sites will commence pending approvals by regulatory authorities and appropriate study sites ethics committees. 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.

Licensing

In January and December 2005, bioMérieux s affiliates exercised options to develop diagnostic products for certain selected undisclosed disease targets using our patented ribosomal RNA technologies pursuant to the terms of a September 2004 agreement. In exchange for these rights, bioMérieux s affiliates paid us $6.6 million in license fees, and $0.25 million as an option fee. We recorded $3.9 million of these fees as license revenue in 2005, based on the number of targets selected and the total number of targets that may be selected by the end of 2006. The amount and timing of additional revenue that we record will depend on the number of additional targets, if any, selected by bioMérieux s affiliates, which have options to develop diagnostic products for other disease targets that they may select by paying us up to an additional $0.9 million by the end of 2006. We will receive royalties on the sale of any products developed by bioMérieux s affiliates using our intellectual property.

In January 2005, we entered into a license agreement with Corixa Corporation, or Corixa, and received the right to develop molecular diagnostic tests for multiple potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancers. Pursuant to the terms of the agreement, we paid Corixa an initial access fee of $1.6 million, an additional $1.6 million in February 2006 and have agreed to pay an additional $1.6 million on January 31, 2007, unless we terminate the agreement prior to that date. We have recorded the collective $3.2 million of license fees as an intangible asset which is being amortized on a straight-line basis to research and development expense over the underlying life of the patents. We also agreed to pay Corixa milestone payments totaling an additional $2.0 million on a product-by-product basis based on

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the occurrence of certain regulatory and/or commercial events. We agreed to pay Corixa additional milestone payments and royalties on net sales of any products developed by us using Corixa s technology.

In December 2004, we entered into a license agreement with AdnaGen AG, or AdnaGen, 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), which have been recorded as research and development, or R&D, expenses, since we have not yet determined technological feasibility and do not currently have alternative future plans to use this technology other than for our prostate cancer development program. Upon the occurrence of certain clinical, regulatory and/or commercial events, we agreed to pay AdnaGen up to three milestone payments totaling an additional $2.25 million. Further, we agreed to pay AdnaGen royalties on net sales of any products we develop using AdnaGen s technology.

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. During this period, we are evaluating the feasibility of adapting Qualigen s immunoassay platform to perform NAT using our proprietary technologies. If we exercise this option, we will purchase 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 would be approximately $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. We recorded the $1.0 million option fee as an intangible asset which is being amortized over the 18-month evaluation period of the option or until execution of the license, whichever comes first.

In September 2004, we entered into a Settlement Agreement and an Amendment to our Non-exclusive License Agreement with Vysis, Inc., or Vysis, under which we withdrew our patent litigation against Vysis and agreed to pay Vysis (which was acquired by Abbott) an aggregate of $22.5 million. This amount included $20.5 million for a fully paid up license to eliminate all of our future royalty obligations to Vysis under the Collins patent covered by the license, and $2.0 million for a fully paid-up, royalty-free license in additional fields under the Collins patent. We had been paying royalties under a pre-existing license agreement which has since been amended. The license now covers current and future products in the field of infectious diseases, as well as potential products in all other fields. Chiron 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. We recorded the $17.0 million net payment ($22.5 million less Chiron s $5.5 million reimbursement) to Vysis as an intangible asset, which is being amortized to cost of goods sold over the patent s remaining economic life of 135 months.

Supply Agreements

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 human papillomavirus, or HPV. We plan to use these oligonucleotides in molecular diagnostic assays. Pursuant to the agreement, we paid Roche manufacturing access fees of $20.0 million in May 2005 and agreed to pay $10.0 million within 10 days of the occurrence of certain future commercial events, but not later than December 1, 2008. We also agreed to pay Roche transfer fees for the HPV oligonucleotides. The initial $20.0 million manufacturing fee has been recorded as an intangible asset which, upon commercialization of the our HPV products, is expected to be amortized to cost of product sales over the economic life of the products.

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Product Development

On December 1, 2005, the FDA granted marketing approval for our West Nile virus, or WNV, assay on the enhanced semi-automated system, or 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. We intend to submit for 510(k) clearance of the TIGRIS instrument for use with the WNV assay in the first part of 2006. We plan to submit a (post-approval) supplement to our WNV Biologics License Application, or BLA, adding the TIGRIS instrument, at approximately the same time.

In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. Also in October 2005, we received a complete review letter from the FDA setting forth questions regarding our BLA for the Procleix Ultrio assay itself. We anticipate submitting a BLA amendment for the Procleix Ultrio assay for use on eSAS, responding to the FDA s questions, by the end of the first quarter of 2006. We anticipate submitting a new 510(k) application for the TIGRIS instrument for use with the Procleix Ultrio assay following clearance of the TIGRIS instrument for use with the WNV assay. We anticipate submitting a (post-approval) BLA supplement for the Procleix Ultrio assay, for use on the TIGRIS instrument, following approval of the BLA for the Procleix Ultrio assay on eSAS. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

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 infections 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. We anticipate filing for regulatory clearance in the United States of a similar application from TriPath s liquid Pap transport media in 2006.

Arbitration Award

In April 2005, we received a Tentative Opinion and Award in our arbitration with Bayer HealthCare, LLC concerning the parties collaboration for the development and sale of nucleic acid diagnostic tests for viral organisms. In June 2005, the arbitrator issued an Interim Opinion and Award that adopted all substantive rulings of the Tentative Opinion and Award. The arbitrator determined that we are entitled to a co-exclusive right to distribute qualitative Transcription-Mediated Amplification, or TMA, assays to detect HCV and HIV-1 for the remaining term of the agreement. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as we requested. As a result of a termination of the agreement, we will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Further, the arbitrator determined that Bayer will be required to reimburse us $2.0 million for our legal fees and expenses related to the arbitration proceedings. In the June 2005 Interim Opinion and Award, the arbitrator also concluded that an additional hearing would be required to determine whether a royalty payment would be required as a result of our exercise of our co-exclusive rights to distribute the qualitative TMA assays for HCV and HIV-1, and, if so, the amount and beneficiary of such royalties. The additional hearing took place in September 2005. On March 3, 2006, the arbitrator issued his Tentative Award following the additional hearing. The arbitrator concluded that Gen-Probe is licensed under the relevant HIV and HCV patents for qualitative assays during the term of the collaboration agreement and that the Company is not obligated to pay Bayer an initial license fee in connection with the sale of those assays. The arbitrator further concluded that the Company will be required to pay running sales royalties to Bayer on the Company s sales of the qualitative TMA assays for HCV and HIV-1. We believe the royalty rates are generally consistent with rates paid by other licensees of the relevant patents. The March 3, 2006 Tentative Award is subject to revision by the arbitrator following comments by the parties. The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within the Judicial

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Arbitration & Mediation Services, Inc., or JAMS. There can be no assurances as to the final outcome of the arbitration.

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 Chiron for the products provided under our collaboration agreements with Chiron prior to regulatory approval, and the payments we receive from Chiron, Bayer Corporation, or Bayer, 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 2005, product sales, collaborative research revenues and royalty and license revenues equaled 89%, 8% and 3%, respectively, of our total revenues of $306.0 million.

Product sales

Our primary source of revenue is the sale of clinical diagnostic and blood screening products in the United States. Our clinical diagnostic products include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During 2005, we shipped approximately 21.4 million tests for the diagnosis of a wide variety of infectious microorganisms, including those causing STDs, tuberculosis, strep throat, pneumonia and fungal infections. The principal customers for our clinical diagnostics products include large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

Since 1999, we have supplied NAT assays for use in screening blood donations intended for transfusion. Our primary blood screening assay detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments are marketed through our collaboration with Chiron 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 Chiron for sales to blood bank facilities located in countries where our products have obtained governmental approvals. Blood screening product sales are then adjusted monthly corresponding to Chiron s payment to us of amounts reflecting our ultimate share of net revenue from sales by Chiron to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Chiron to third-parties, less freight, duty and certain other adjustments specified in our agreement with Chiron, multiplied by our share of the net revenue. Our share of the net revenue was 43.0% with respect to sales of assays that include a test for HCV beginning the second quarter of 2002 (following FDA approval in February 2002) upon implementation of commercial pricing, through April 6, 2003, after which our share of net revenues from sales of assays that include a test for HCV was adjusted to 47.5%. Effective January 1, 2004, our share of net revenues from commercial sales of assays that include a test for HCV was permanently changed to 45.75% under our agreement with Chiron. With respect to commercial sales of blood screening assays under our collaboration with Chiron that do not include a test for HCV, such as possible future commercial tests for WNV, we will receive 50% of net revenues after deduction of appropriate expenses. Our costs related to these products primarily include manufacturing costs.

Collaborative research revenue

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 2005 and 2004, we recognized $18.4 million and $18.5 million, respectively, as collaborative research revenue through our collaboration with Chiron from deliveries of WNV tests on a cost recovery basis. In 2005 and 2004, we recognized $2.0 million and $1.4 million respectively, in reimbursements for expenses incurred for WNV development research as collaborative research revenue. We expect to discontinue recognizing these sales as collaborative research revenue upon first shipment of the FDA

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approved and labeled product. In December 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. We intend to submit for 510(k) clearance of the TIGRIS instrument for use with the WNV assay in the first part of 2006. We plan to submit a (post-approval) supplement to our WNV assay BLA, adding the TIGRIS instrument, at approximately the same time.

In March 2003, we signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. In each of 2005 and 2004, we recognized $2.8 million in reimbursements for expenses incurred related to the development of this assay. We expect to receive further reimbursement from Chiron for certain costs incurred during the development of the Procleix Ultrio and WNV assays. In January 2004, we commenced clinical trials of the Procleix Ultrio assay in the United States on our TIGRIS instrument. In September 2004, we filed a BLA with the FDA for this assay. In October 2005, we received a complete review letter from the FDA setting forth additional questions regarding our BLA for the Procleix Ultrio assay. We anticipate submitting a BLA amendment for the Procleix Ultrio assay for use on eSAS, responding to FDA s questions, by the end of the first quarter of 2006. We anticipate submitting a new 510(k) application for the TIGRIS instrument for use with the Procleix Ultrio assay following clearance of the TIGRIS instrument for use with the WNV assay. We anticipate submitting a (post-approval) BLA supplement for the Procleix Ultrio assay, for use on the TIGRIS instrument, following approval of the BLA for the Procleix Ultrio assay on eSAS. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

We recognize collaborative research revenue over the term of certain strategic alliance agreements with Chiron and others as reimbursable costs are incurred. The costs associated with the reported collaborative research revenue are based on fully burdened full time equivalent, or FTE, rates and are reflected in our 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 our blood screening development collaboration with Chiron and, therefore, are not able to quantify all of the direct costs associated with collaborative research revenue.

Royalty and license revenue

We recognize non-refundable up-front license fees over the performance period of an agreement or at the time that we have satisfied all substantive performance obligations of an agreement. We also receive milestone payments for successful achievement of contractual development activities. 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 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.

Under the strategic alliance agreement we entered into with Chiron in June 1998, we have responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Chiron has responsibility for marketing, distribution and service of the blood screening products worldwide. During 2004, we recognized as royalty and license revenue, a $6.5 million milestone payment from Chiron as we commenced clinical trials of the Procleix Ultrio assay on our TIGRIS instrument in the United States. Under the terms of the agreement, an additional payment of $10.0 million is due to us in the future if we obtain FDA approval of our Procleix Ultrio assay for use on the TIGRIS instrument. There is no guarantee we will achieve this milestone and receive any additional milestone payments under this agreement. In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. Also in October 2005, we received a complete review letter from the FDA setting forth additional questions regarding our BLA for the Procleix Ultrio assay itself. There can be no assurance that these products will receive regulatory clearance by the FDA.

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Cost of product sales

Cost of product sales includes direct material, direct labor, and manufacturing overhead associated with the production of inventory on a standard cost basis. 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 and 2004, our manufacturing facilities produced development lots for WNV and Procleix Ultrio assays. The majority of costs associated with these development lots are classified as research and development expense. The portion of a development lot that is manufactured for commercial sale outside the United States is capitalized to inventory and classified as cost of product sales upon shipment.

Our blood screening manufacturing facility has and will continue to operate below its potential capacity for the foreseeable future. A portion of this available capacity is utilized for research and development 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 research and development expense prior to FDA approval.

In 2005, the growth in blood screening revenues was partially driven by sales of TIGRIS instruments to Chiron totaling approximately $9.0 million. Under our contract with Chiron, 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 higher 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 strategic partners. R&D spending is expected to increase in the future due to new product development, clinical trial costs and clinical manufacturing costs; 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 related to the technologies covered by the license.

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 developmental lots and clinical trial lots for our blood screening products and with further development of our TIGRIS instrument. Collaborative research revenues associated with these types of costs have at times been realized in a period later than when the costs were incurred due to the need for clarification on the extent of reimbursable costs.

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 invento-

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ries, long-lived assets including patent costs and capitalized software, and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of 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.

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

Revenue recognition

We record shipments of our clinical diagnostic products as product sales when the product is shipped and title and risk of loss has passed and when collection of the resulting receivable is reasonably assured. Revenue from our blood screening products shipped to countries where regulatory approval has been received is recorded as product sales based on a contracted transfer price with our third-party collaboration partner, Chiron. Based on the terms of our agreement with Chiron, our ultimate share of the net revenue from sales to the end user is not known until reported to us by Chiron.

We manufacture our blood screening products according to Chiron s demand specifications and transfer completed product to Chiron s virtual warehouse, which is located on our premises. Upon transfer to Chiron s virtual warehouse, we bill Chiron at an agreed upon transfer price, and Chiron remits payment within 30 days. In the past, we recorded all amounts billed as deferred revenue until shipment from the virtual warehouse to Chiron s end-customers or Chiron s international warehouse; upon which we then recognized blood screening product sales at the transfer price and recorded the related cost of products sold. We then adjusted blood screening product sales upon our receipt of customer revenue reports and a net payment from Chiron of amounts reflecting our ultimate share of net sales by Chiron of these products, less the transfer price revenues previously paid.

During 2005, our U.S. blood screening sales increased by approximately $5.4 million due to the recognition of previously deferred revenue resulting from our shipment of Chiron controlled blood screening products from Chiron s virtual warehouse to their recently established third party warehouse, rather than directly to their end-customers.

Product sales 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 Chiron for use in blood screening and record these instrument sales upon delivery since Chiron 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 Company 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 record as collaborative research revenue shipments of our blood screening products in the United States and other countries in which the products have not received regulatory approval. We do this because price restrictions apply to these products prior to FDA marketing approval in the United States and

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similar approvals in foreign countries. Upon first shipment of FDA approved and labeled product following commercial approval, we classify sales of these products as product sales in our financial statements.

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 agreement. 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 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.

We recognize royalty revenue related to 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.

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 inventory balances for estimated excess and obsolete inventory equal to the difference between the cost of such inventory 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 inventory 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 inventory valuation reserves may be required.

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

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.

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Factors we consider important which 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.

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, 2005, capitalized software development costs related to our TIGRIS instrument totaled $21.0 million, net of accumulated amortization. We completed beta evaluations of this instrument for clinical diagnostic applications and undertook initial beta trials for blood screening applications before we completed a clinical trial for a diagnostic application in June 2003. In December 2003, we received approval from the FDA for testing our APTIMA Combo 2 assay on the TIGRIS instrument. We initiated clinical trials of our Procleix Ultrio assay on our TIGRIS instrument for a blood screening application in January 2004 and filed a BLA with the FDA for this assay in September 2004. In October 2005, the FDA notified us that it considers our TIGRIS instrument for blood screening not substantially equivalent to our already cleared eSAS for screening donated human blood with the Procleix Ultrio assay. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. If we are not able to successfully deliver this instrument to the marketplace and attain customer acceptance, the asset could be impaired and an adjustment to the carrying value of this asset would be considered by management at that time.

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

In February 2005, we entered into a supply and purchase agreement with Roche whereby Roche agreed to manufacture and supply us with oligonucleotides for HPV, which we plan to use in molecular diagnostic assays. Under this agreement, we paid Roche manufacturing access fees of $20.0 million in May 2005 and expect to pay $10.0 million no later than December 2008. The initial $20.0 million manufacturing access fee has been recorded as an intangible asset that, upon commercialization of our HPV oligonucleotides, will be amortized to cost of product sales over the economic life of the products. Periodically, we perform an impairment analysis to determine if we expect to recover these costs through the future sales of HPV products. A decrease in forecasted sales may result in impairment charges in the future. We expect to develop an HPV test and our current sales forecast indicates the payment is recoverable.

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Income taxes

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

Future accounting requirements

In December 2004, the Financial Accounting Standards Board, FASB, issued revised Statement 123, or SFAS No. 123(R), Share-Based Payment, which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced that the accounting provisions of SFAS No. 123(R) will be effective for the first quarter of 2006. We plan on adopting the provisions of SFAS 123(R) using the modified prospective application, which provides for certain changes to the method for valuing share-based compensation. Under the modified prospective application, prior periods are not revised for comparative purposes. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. At December 31, 2005, unamortized compensation expense related to outstanding unvested options, as determined in accordance with SFAS No. 123, was approximately $30.0 million before income taxes. In 2006, we will begin to record this unamortized amount as stock compensation expense pursuant to the vesting schedules of the underlying option awards. We will incur additional expense related to new awards granted after 2005 that cannot yet be quantified.

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Results of Operations

	Years Ended December 31,			% Change	
	2005	2004	2003	05/04	04/03
	(In millions)				
Statement of income:					
Revenues:					
Product sales	$ 271.7	$ 222.6	$ 188.6	22 %	18 %
Collaborative research revenue	25.8	27.1	15.4	(5)%	76 %
Royalty and license revenue	8.5	20.0	3.2	(58)%	525 %
Total revenues	306.0	269.7	207.2	13 %	30 %
Operating expenses:					
Cost of product sales	83.9	59.9	45.5	40 %	32 %
Research and development	71.9	68.5	63.6	5 %	8 %
Marketing and sales	31.1	27.2	22.6	14 %	20 %
General and administrative	32.1	31.6	23.2	2 %	36 %
Total operating expenses	219.0	187.2	154.9	17 %	21 %
Income from operations	87.0	82.5	52.3	5 %	58 %
Total other income, net	4.7	2.1	2.8	124 %	(25)%
Income tax expense	31.6	30.0	19.8	5 %	52 %
Net income	$ 60.1	$ 54.6	$ 35.3	10 %	55 %
Net income per share					
Basic	$ 1.19	$ 1.10	$ 0.74	8 %	49 %
Diluted	$ 1.15	$ 1.06	$ 0.72	8 %	47 %
Weighted average shares outstanding					
Basic	50.6	49.4	48.0		
Diluted	52.4	51.4	49.1		

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

Product sales

Product sales increased 22% to $271.7 million in 2005 from $222.6 million in 2004. The $49.1 million increase was primarily attributed to $13.6 million in higher instrument sales, $22.6 million in higher blood screening sales, and $21.9 million in higher APTIMA Combo 2 assay sales, partially offset by a $6.8 million decrease in PACE product sales. 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. Further, the current year s product sales included approximately $5.4 million due to the recognition of previously deferred revenue related to United States blood screening products shipped to Chiron s recently established third party warehouse, rather than directly to Chiron s end customers.

Product sales increased 18% to $222.6 million in 2004 from $188.6 million in 2003. The $34.0 million increase was principally the result of $16.4 million in higher blood screening sales, both in the United States and international markets, a $3.8 million increase in instrument sales, and a $13.1 million increase in STD product sales, primarily APTIMA. Blood screening sales represented $95.6 million, or 43% of product sales in 2004, compared to $76.6 million, or 41% of product sales, in 2003.

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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 into both the STD and blood screening markets, and continuing pricing pressure as it relates to the STD market.

Collaborative research revenue

Collaborative research revenue decreased 5% in 2005 from 2004. The $1.3 million decrease 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 Chiron for WNV assay development costs and $1.3 million in revenue for shipments of discriminatory HBV, or dHBV, assays and TIGRIS instrument lease revenue from Chiron.

Collaborative research revenue increased 76% in 2004 from 2003. The $11.7 million increase was primarily the result of a $12.6 million increase in firm support commitment payments in connection with the WNV assay tests provided to United States customers through our collaboration with Chiron, and a $1.4 million increase in revenue for reimbursement from Chiron for WNV assay development costs. This increase was partially offset by a $1.9 million decrease in revenue from the NIH as our WNV assay funding was completed during 2004 and a $1.2 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay.

Collaborative research revenue tends to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative research revenues, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate additional collaborative research revenues depends, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners. These relationships may not be established or maintained and current collaborative research revenue may decline. In the event of FDA approval of our Procleix Ultrio assay, we would expect Chiron to implement commercial pricing related to the use of this product in the United States, which would result in an increase in product sales partially offset by a decrease in collaborative research revenue.

Royalty and license revenue

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, which was based on the selection of targets pursuant to the terms of our September 2004 agreement with bioMérieux, and a $1.4 million increase in our share of royalties from Chiron based upon Chiron s agreement with Laboratory Corporation of America for use of Chiron s HCV intellectual property for NAT used in screening plasma donations in the United States.

Royalty and license revenue increased 525% in 2004 from 2003. The $16.8 million increase was principally attributed to (i) $7.0 million in license fees earned from Tosoh as part of our non-exclusive licensing agreement relating to NAT technologies effective in January 2004, and (ii) a $6.5 million milestone payment from Chiron as we began clinical trial testing of the Procleix Ultrio assay on our TIGRIS instrument in the United States. Further, we recognized $3.2 million of license revenue from Bayer during 2004 for the licensing of rights to certain patented technology.

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.

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Cost of product sales

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 Chiron ($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 ($0.8 million) related to our TIGRIS instrument, which began in the second quarter of 2004.

Cost of product sales increased 32% in 2004 from 2003. The $14.4 million increase was principally attributed to higher product shipments ($8.5 million), higher allowances for scrap expense ($4.4 million) and the amortization of capitalized software development costs ($1.7 million) related to our TIGRIS instrument, which began in the second quarter of 2004.

Our gross profit margin as a percentage of product sales decreased to 69% in 2005, from 73% in 2004 and 76% in 2003. The decrease in gross profit margin percentage in 2005 from 2004 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 had lower margin rates than domestic sales, and the amortization of capitalized software development costs, which began in the second quarter of 2004. The 2004 percentage decrease from 2003 was primarily the result of higher scrap expense, including expiration of enzymes that were produced in support of the Procleix Ultrio assay BLA, increased sales of lower margin products (including TIGRIS instruments), and the amortization of capitalized software development costs, which began in the second quarter of 2004, partially offset by lower unit costs on sales volume increases.

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

We anticipate that requirements for smaller pool sizes or ultimately individual donor testing of blood samples, if and when implemented, could result in lower gross margin percentages, as additional tests would be required to deliver the sample results, unless a corresponding increase in sales pricing structure is implemented. We are not able to accurately predict the timing and extent to which our gross margin percentage may be negatively affected as a result of smaller pool sizes or individual donor testing because we do not know the ultimate selling price that Chiron, our distributor, would charge to the end user if smaller pool sizes or individual donor testing were implemented. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion may lead to lower gross margin percentages.

Research and development

Our R&D expenses include salaries and other personnel-related expenses, temporary personnel, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. R&D expenses increased 5% in 2005 from 2004. The $3.4 million increase was primarily due to higher staffing levels to support development projects, such as prostate cancer and HPV ($7.0 million), 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).

R&D expenses increased 8% in 2004 from 2003. The $4.9 million increase was primarily due to higher staffing levels to support product development projects and clinical trial efforts ($9.0 million), an increase in clinical trials for blood screening products ($2.2 million), an increase in outside development research due to our aggregate license fees paid to DiagnoCure and AdnaGen AG ($1.6 million), and an increase in R&D expenses from our subsidiary, Molecular Light Technology Limited, or MLT, acquired in August 2003 ($1.2 million). These increases were mostly offset by a $9.3 million decrease in development lot production and lower per unit costs.

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Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased 14% in 2005 from 2004. The $3.9 million increase was primarily due to a $3.2 million increase in salaries, benefits, commissions and other personnel related costs in our marketing, sales, and technical service organization, together with a $0.6 million 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.

Marketing and sales expenses increased 20% in 2004 from 2003. The $4.6 million increase was primarily due to a $3.7 million increase in salaries, benefits, commissions and other personnel related costs in our marketing, sales, and technical service organization in order to support APTIMA market expansion and TIGRIS instrument commercialization, and a $0.6 million increase for advertising and promotional costs related to the marketing launch of our TIGRIS instrument.

General and administrative

Our general and administrative, or 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 2% in 2005 from 2004. The $0.5 million increase was primarily the result of a $1.4 million increase in salaries, benefits and other personnel related expenses, and a $0.7 million increase in recruiting and relocation fees. 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.

G&A expenses increased 36% in 2004 from 2003. The $8.4 million increase was primarily the result of a $3.0 million increase in salaries, benefits and other expenses resulting from higher staffing levels, including $1.0 million in expenses from our majority owned subsidiary, MLT; a $3.6 million increase in patent and legal related expenses, including the costs of our ongoing arbitration with Bayer; and a $0.7 million non-cash compensation charge related to the departure of a former executive.

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 $2.6 million net increase 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.

The $0.7 million net decrease in total other income in 2004 from 2003 was primarily due to a $0.5 million increase in realized foreign exchange rate losses.

Income tax expense

Income tax expense increased 5% in 2005 from 2004 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.

Income tax expense increased 52% in 2004 from 2003, to 35.5% of 2004 pretax income, compared to 35.9% of 2003 pretax income. The slight decrease in our effective tax rate in 2004 was principally attributed to an increase in tax-exempt interest income, partially offset by higher profits taxed at the combined federal and state statutory tax rate of approximately 41%.

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Liquidity and capital resources

	2005	2004	2003	Amount Change From 2004 to 2005
			(In thousands)	
December 31:				
Cash, cash equivalents and short-term investments	$ 220,288	$ 193,826	$ 156,306	$ 26,462
Working capital	262,659	234,202	169,000	28,457
Current ratio	6:1	8:1	5:1	
Year Ended December 31:				
Cash provided by (used in):				
Operating activities	$ 85,860	$ 62,284	$ 52,616	$ 23,576
Investing activities	(97,103)	(93,712)	(74,787)	(3,391)
Financing activities	18,696	20,438	14,888	(1,742)
Purchases of property, plant and equipment (included in investing activities above)	(45,386)	(26,021)	(12,238)	(19,365)

Historically, we have financed our operations through cash from operations, cash received from collaborative research agreements, royalty and license fees, and cash from capital contributions. At December 31, 2005, we had $220.3 million of cash and cash equivalents and short-term investments.

The $23.6 million increase in net cash provided by operating activities during 2005 from 2004 included a $4.7 million growth in net current and deferred income taxes payable, a $5.5 million increase in net income, a $9.9 million increase in accounts payable, a $4.6 million decrease in net inventory purchases, and a $4.4 million increase in depreciation and amortization; partially offset by a $5.4 million decrease in stock option income tax benefits. The accounts payable change was attributed to acceleration of payments to our vendors in December 2004, immediately prior to our implementation of a new Enterprise Resource Planning, or ERP, software system. The increase in depreciation and amortization was primarily due to amortization on additional technology and software licenses that were purchased, along with the amortization of capitalized software development costs, which began in the second quarter of 2004. The decrease in net inventory purchases in 2005 from 2004 was attributed to the 2004 commercialization of our TIGRIS instrument and the European launch of the Procleix Ultrio assay.

The $3.4 million increase in our investing activities during 2005 included a $19.4 million increase in capital expenditures and a $6.8 million increase in purchases of various manufacturing, license and access fess, including a $20.0 million manufacturing fee paid to Roche. Further, during 2005, we paid $1.5 million plus accrued interest to acquire the remaining outstanding shares of MLT and $2.5 million for preferred shares of Molecular Profiling Institute, Inc. These increases were partially offset by a $26.6 million decrease in purchases (net of sales) of short-term investments. Our 2005 growth in capital expenditures was primarily due to the construction of our new building and costs of our ERP system implementation. 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. We expect capital expenditures in 2006 to approximate 2005 spending.

The $1.7 million decrease in net cash provided by financing activities during 2005 from 2004 was principally attributed to a $0.8 million decrease in employee purchases of our common stock made through our Employee Stock Purchase Plan, or ESPP, and a $0.9 million decrease in proceeds from the exercise of stock options. On a

going-forward basis, cash from financing activities will 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.

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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%. We have not taken advances against the line of credit since its inception. The line of credit agreement requires us to comply with various financial and restrictive covenants. As of December 31, 2005, we were in compliance with all covenants.

In July 2004, we commenced construction of an additional building to expand our main San Diego campus. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 190,000 square feet built-out with interior improvements. The additional space that will not initially be built-out will allow for future expansion. The first phase of this project is currently estimated to cost approximately $44.4 million, of which $32.1 million was capitalized to construction in-progress as of December 31, 2005. These costs are being capitalized as incurred and depreciation will commence upon our completion and use of the building, which is planned for mid 2006.

We implemented a new ERP system that cost approximately $4.9 million in 2004. We incurred $3.3 million in additional costs during 2005 and expect to incur approximately $1.0 to $2.0 million of costs in 2006 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, 2005 were as follows (in thousands):

	Total	2006	2007	2008	2009	2010	Thereafter
Operating leases[1]	$ 3,165	$ 2,065	$ 863	$ 167	$ 70	$	$
Material purchase commitments[2]	22,582	22,582					
Collaborative commitments[3]	19,900	6,500	2,650	10,000	750		
Total[4]	$ 45,647	$ 31,147	$ 3,513	$ 10,167	$ 820	$	$

(1) Reflects obligations on facilities under operating leases in place as of December 31, 2005. 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 $14.4 million expected to be purchased for TIGRIS instruments, we anticipate that approximately $9.3 million will be reimbursed by Chiron.

(3) In addition to the minimum payments due under our collaborative agreements, we may be required to pay up to $4.25 million in milestone payments, plus royalties on net sales of any products using specified technology. Further, if we exercise our option to develop a point of sample NAT instrument, we are required to purchase an equity interest in Qualigen for approximately $7.0 million and we may pay up to $3.0 million based on development milestones.

(4) Does not include amounts relating to our obligations under our collaboration with Chiron, pursuant to which both parties have obligations to each other. We are obligated to manufacture and supply our blood screening assay to Chiron, and Chiron 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 Chiron intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

As discussed in Note 12 to the Consolidated Financial Statements, we have long-term liabilities for deferred employee compensation. The payments related to the deferred compensation are not included in the table above since

they are dependent upon when certain key employees retire or otherwise leave the Company.

Our primary short-term needs for capital, which are subject to change, are for expansion of our San Diego campus, continued research and development of new products, costs related to commercialization of blood screening products and purchases of the TIGRIS instrument for placement with our customers. Certain research and development costs may be funded under collaboration agreements with partners.

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We believe that our available cash balances, anticipated cash flows from operations and proceeds from stock option exercises, and available line of credit, will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to covenants restricting our operations. 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.

Stock Options

Option program description

Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our primary program consists of a broad-based plan under which stock options are granted to employees and directors. Substantially all of our employees have historically participated in our stock option program.

Additional information regarding our stock option plans for 2005, 2004 and 2003 is provided in our consolidated financial statements. See Notes to Consolidated Financial Statements, Note 8 Stockholders Equity.

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General option and equity compensation plan information

Summary of Option and Restricted Stock Activity
(Shares in thousands)

		Options Outstanding			
	Shares Remaining Available for Future Issuance	Number of Shares to be Issued Upon Exercise	Weighted Average Exercise Price	Restricted Stock Awards	Director Stock Purchases
December 31, 2003	3,647	5,473	$ 18.10	20	
Grants	(2,084)	2,061	37.21	20	3
Exercises		(1,178)	14.15		(3)
Cancellations	352	(352)	24.97		
December 31, 2004	1,915	6,004	$ 25.03	40	
Grants	(1,363)	1,228	43.82	132	3
Exercises		(890)	17.65		(3)
Cancellations	388	(388)	32.78		
December 31, 2005	940	5,954	$ 29.53	172*	

* Includes 60,000 shares of Deferred Issuance Restricted Stock and 112,000 shares of Restricted Stock as of December 31, 2005.

In-the-Money and Out-of-the-Money Option Information
(Shares in thousands)

	Exercisable		Unexercisable		Total	
As of December 31, 2005	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg Exercise Price
In-the-Money	2,940	$ 22.35	2,840	$ 35.74	5,780	$ 28.93
Out-of-the Money[(1)]			174	49.36	174	49.36
Total Options Outstanding	2,940		3,014		5,954	

(1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of our common stock, $48.79, at the close of business on December 30, 2005.

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 $3.0 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.

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Foreign Currency Exchange Risk

Although the majority of our revenue is realized in United States dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. The functional currencies of our wholly owned subsidiaries is the British pound. Accordingly, the accounts of these operations are translated from the local currency 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, 2005 were not material. Under our collaboration agreement with Chiron, 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 Chiron s 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 2005, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $3.3 million. We believe that our business operations are not exposed to market risk relating to commodity price risk.

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-31.

Item 9. ***Changes in and Disagreements with Independent Registered Public Accounting Firm 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

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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 2005.

Changes in Internal Control Over Financial Reporting

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

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005 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, 2005.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 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, 2005, 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, 2005, 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, 2005, 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, 2005 and 2004, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2005 of Gen-Probe Incorporated and our report dated February 9, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 9, 2006

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

None.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by this Item will be set forth in the section headed Proposal 1 Election of Directors and the section headed Executive Compensation and Other Information in our definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders (the Proxy Statement), to be held in 2006, and is incorporated in this report by reference.

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 will be set forth in the section headed Executive Compensation and Other Information and the section headed Security Ownership of Certain Beneficial Owners and Management in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in the section headed Security Ownership of Certain Beneficial Owners and Management and the section headed Executive Compensation and Other Information in the Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans, is set forth in Item 7 of this report, entitled Management s Discussion and Analysis of Financial Condition and Results of Operations, Stock Options General option and equity compensation plan information , and will be set forth in the section entitled Executive Compensation Equity Compensation Plan Information in our Proxy Statement and is incorporated in this report by reference.

Item 13. ***Certain Relationships and Related Transactions***

The information required by this Item will be set forth in the section headed Certain Transactions in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this Item will be set forth in the section headed Independent Registered Public Accounting Firm Fees in the Proxy Statement, and is incorporated in this report by reference.

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PART IV

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

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

1. The following financial statements of Gen-Probe Incorporated and Reports 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, 2005 and 2004

Consolidated statements of income for each of the three years in the period ended December 31, 2005

Consolidated statements of cash flows for each of the three years in the period ended December 31, 2005

Consolidated statements of stockholders equity for each of the three years in the period ended December 31, 2005

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, 2005

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: March 10, 2006

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)	March 10, 2006
/s/ Herm Rosenman Herm Rosenman	Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 10, 2006
/s/ John W. Brown John W. Brown	Director	March 10, 2006
/s/ Raymond V. Dittamore Raymond V. Dittamore	Director	March 10, 2006
/s/ Mae C. Jemison, M.D Mae C. Jemison, M.D	Director	March 10, 2006
/s/ Armin M. Kessler Armin M. Kessler	Director	March 10, 2006
/s/ Gerald D. Laubach, Ph.D. Gerald D. Laubach, Ph.D.	Director	March 10, 2006
/s/ Brian A. McNamee, M.B.B.S Brian A. McNamee, M.B.B.S	Director	March 10, 2006

/s/ Phillip M. Schneider	Director	March 10, 2006
Phillip M. Schneider		
/s/ Abraham D. Sofaer	Director	March 10, 2006
Abraham D. Sofaer		

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GEN-PROBE INCORPORATED
CONSOLIDATED FINANCIAL STATEMENTS
CONTENTS

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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, 2005 and 2004, and the related consolidated statements of income, cash flows and stockholders equity for each of the three years in the period ended December 31, 2005. 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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Gen-Probe Incorporated s internal control over financial reporting as of December 31, 2005, 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 9, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 9, 2006

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GEN-PROBE INCORPORATED
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31	
	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,328	$ 25,498
Short-term investments	187,960	168,328
Trade accounts receivable, net of allowance for doubtful accounts of $790 and $664 at December 31, 2005 and 2004, respectively	31,930	21,990
Accounts receivable other	1,924	3,136
Inventories	36,342	27,308
Deferred income taxes	10,389	7,725
Prepaid expenses	10,768	8,517
Other current assets	4,184	5,447
Total current assets	315,825	267,949
Property, plant and equipment, net	105,190	76,651
Capitalized software	20,952	23,466
Goodwill	18,621	18,621
License, manufacturing access fees and other assets	49,648	24,395
Total assets	$ 510,236	$ 411,082
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	14,029	6,729
Accrued salaries and employee benefits	14,910	11,912
Other accrued expenses	3,264	4,451
Income tax payable	13,192	1,188
Deferred revenue	7,771	9,467
Total current liabilities	53,166	33,747
Deferred income taxes	5,124	9,187
Deferred revenue	4,333	5,000
Deferred rent	240	309
Minority interest		1,810
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, 51,137,541 and 50,035,490 shares issued and outstanding at December 31, 2005 and 2004, respectively	5	5

Additional paid-in capital	281,907	248,767
Deferred compensation	(5,951)	(1,104)
Accumulated other comprehensive (loss) income	(1,231)	807
Retained earnings	172,643	112,554
Total stockholders equity	447,373	361,029
Total liabilities and stockholders equity	$ 510,236	$ 411,082

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		
	2005	2004	2003
Revenues:			
Product sales	$ 271,650	$ 222,560	$ 188,645
Collaborative research revenue	25,843	27,122	15,402
Royalty and license revenue	8,472	20,025	3,144
Total revenues	305,965	269,707	207,191
Operating expenses:			
Cost of product sales	83,900	59,908	45,458
Research and development	71,846	68,482	63,565
Marketing and sales	31,145	27,191	22,586
General and administrative	32,107	31,628	23,233
Total operating expenses	218,998	187,209	154,842
Income from operations	86,967	82,498	52,349
Total other income, net	4,727	2,081	2,747
Income before income taxes	91,694	84,579	55,096
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
Weighted average shares outstanding:			
Basic	50,617	49,429	47,974
Diluted	52,445	51,403	49,137

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		
	2005	2004	2003
Operating activities			
Net income	$ 60,089	$ 54,575	$ 35,330
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	22,606	18,239	15,822
Stock compensation charges	920	1,142	149
Loss on disposal of property and equipment	399	377	102
Stock option income tax benefits	8,677	14,035	4,387
Changes in assets and liabilities:			
Accounts receivable	(8,937)	(6,774)	(2,164)
Inventories	(9,048)	(13,621)	(688)
Prepaid expenses	(2,251)	(1,428)	(2,626)
Other current assets	1,263	(2,333)	(2,463)
Accounts payable	7,329	(2,535)	310
Accrued salaries and employee benefits	2,998	242	2,710
Other accrued expenses	(1,089)	(2,329)	(259)
Income tax payable	12,053	(4,965)	5,297
Deferred revenue	(2,363)	2,119	(1,085)
Deferred income taxes	(6,717)	5,567	(2,239)
Deferred rent	(69)	(14)	(4)
Minority interest		(13)	37
Net cash provided by operating activities	85,860	62,284	52,616
Investing activities			
Proceeds from sales and maturities of short-term investments	116,907	159,301	42,722
Purchases of short-term investments	(137,841)	(206,822)	(95,421)
Cash paid for acquisition of Molecular Light Technology Limited	(1,539)	(376)	(4,133)
Purchases of property, plant and equipment	(45,386)	(26,021)	(12,238)
Capitalization of intangible assets, including license, manufacturing access fees	(29,117)	(19,836)	(5,705)
Other assets	(127)	42	(12)
Net cash used in investing activities	(97,103)	(93,712)	(74,787)
Financing activities			
Proceeds from issuance of common stock	18,696	20,438	14,888
Net cash provided by financing activities	18,696	20,438	14,888

Effect of exchange rate changes on cash and cash equivalents	(623)	515	138
Net increase (decrease) in cash and cash equivalents	6,830	(10,475)	(7,145)
Cash and cash equivalents at the beginning of year	25,498	35,973	43,118
Cash and cash equivalents at the end of year	$ 32,328	$ 25,498	$ 35,973
Supplemental disclosure of cash flow information:			
Cash paid for:			
Interest	$ 162	$ 34	$ 63
Income taxes	$ 16,807	$ 16,030	$ 11,913

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(In thousands)

	Common Stock		Additional Paid-In	Deferred	Accumulated Other Comprehensive (Loss)	Retained	Total Stockholders
	Shares	Amount	Capital	Compensation	Income	Earnings	Equity
Balance at December 31, 2002	47,600	5	192,624		300	22,649	215,578
Common shares issued from exercise of stock options	1,083		14,301				14,301
Purchase of common shares through employee stock purchase plan	35		587				587
Issuance of common shares to board members	4		87				87
Deferred compensation related to grant of restricted stock awards			600	(600)			
Amortization of deferred compensation				62			62
Stock option income tax benefits			4,387				4,387
Comprehensive income:							
Net income						35,330	35,330
Unrealized gains on short-term investments, net of income tax expense of $61					43		43
Comprehensive income							35,373
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
Issuance of common shares to board members	3		140				140
Deferred compensation related to grant of			839	(839)			

restricted stock awards							
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
Issuance of common shares to board members	4		136				136
Deferred compensation related to grant of restricted stock awards	112		5,631	(5,631)			
Amortization of deferred compensation				784			784
Stock option income tax benefits			8,677				8,677
Comprehensive income:							
Net income						60,089	60,089
Unrealized losses on short-term investments, net of income tax benefits of $496					(950)		(950)
Foreign currency translation adjustment					(1,088)		(1,088)
Comprehensive income							58,051
	51,138	$ 5	$ 281,907	$ (5,951)	$ (1,231)	$ 172,643	$ 447,373

Balance at December 31, 2005

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 customers are large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

In August 2003, the Company paid approximately $7,258,000 in cash to acquire an additional 65.6% of the outstanding shares of Molecular Light Technology Limited (MLT), a privately held company located in Cardiff, Wales. In August 2004, the Company paid $376,000 plus accrued interest, in cash, to acquire an additional 3.4% of the outstanding shares. In May 2005, the Company paid $1,539,000 plus accrued interest, in cash, to acquire the remaining outstanding shares of MLT, giving the Company 100% ownership. As such, the minority interest on the balance sheet has been eliminated and all subsequent earnings (losses) of this subsidiary are fully consolidated into the Company s consolidated financial statements.

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales and Services, Inc., Gen-Probe UK Limited (GP UK Limited) and 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 accounting principles generally accepted in the United States (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 inventories and long-lived assets, including capitalized software, manufacturing and license fees, and income taxes. 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, all 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

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GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Segment information

The Company identifies its operating segments based on business activities, management responsibility and geographical location. For all periods presented, the Company operated in a single business segment. Revenue by geographic location is presented in Note 10.

Concentration of credit risk

The Company sells its diagnostic products primarily to established large reference laboratories, public health laboratories 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

Deferred issuance restricted stock awards

In each of May 2005, June 2004 and August 2003, the Company granted to its chief executive officer 20,000 shares of Deferred Issuance Restricted Stock Awards under the 2003 Incentive Award Plan of the Company (the 2003 Plan), resulting in deferred compensation of $871,000, $839,000 and $600,000, respectively, associated with these grants. The deferred compensation is being amortized to expense on a straight-line basis over the vesting periods (48 months) of the Deferred Issuance Restricted Stock Awards. For the years ended December 31, 2005, 2004 and 2003, the Company recorded $487,000, $273,000 and $62,000, respectively in stock-based compensation expense related to these Deferred Issuance Restricted Stock Awards. At December 31, 2005, there was $1,488,000 remaining in unamortized deferred compensation. The estimated amortization expense of the deferred compensation on the Deferred Issuance Restricted Stock Awards as of December 31, 2005, is $577,000 for 2006, $515,000 in 2007, $305,000 in 2008 and $91,000 in 2009.

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GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Restricted stock awards

In October 2005, the Company granted 112,000 shares of restricted stock to certain executive officers and key employees under the 2003 Plan, resulting in deferred compensation of $4,760,000 associated with these grants. The deferred compensation for these restricted stock awards is based on the number of shares granted multiplied by the fair value of the stock on the date of grant, which is being amortized as stock-based compensation expense over the vesting period (48 months) of the restricted stock awards. For the year ended December 31, 2005, the Company recognized $297,000 in stock-based compensation expense related to these awards. At December 31, 2005, there was $4,463,000 remaining in unamortized deferred compensation. The estimated amortization expense of the deferred compensation on the restricted stock awards as of December 31, 2005, is $1,190,000 for each of 2006, 2007 and 2008 and $893,000 for 2009.

Common stock

The Company also issued 3,138, 3,660 and 3,718 shares of common stock under the 2003 Plan during the years ended December 31, 2005, 2004 and 2003, to members of the Board of Directors as partial consideration for services rendered, resulting in an expense totaling $136,000, $140,000 and $87,000, respectively, which was equal to the fair market value on the date of grants.

Stock options and employee stock purchase plan

The Company accounts for employee stock-based compensation pursuant to APB Opinion No. 25, Accounting for Stock Issued to Employees. Using the intrinsic value method of accounting under APB No. 25, no compensation expense is recognized because the exercise price of the Company s employee stock awards equals the market price of the underlying stock on the date of grant.

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net income and earnings per share have been estimated at the date of grant using the minimum value option pricing model from the Company s stock option plans inception date in August 2000 through September 15, 2002 and the Black-Scholes option-pricing model for all option grants made subsequent to that date when the Company s shares began to be publicly traded. The fair value of each purchase right issued under the Company s Employee Stock Purchase Plan (ESPP) for the years ended December 31, 2005, 2004 and 2003 was estimated on the date of grant using the Black-Scholes pricing model.

During the year ended December 31, 2004, the Company recorded an option-related non-cash compensation charge of approximately $729,000 related to the departure of a former executive.

The following weighted average assumptions were used:

	Stock Option Plans			ESPP		
	2005	2004	2003	2005	2004	2003
Risk-free interest rate	3.97%	3.18%	2.76%	3.04%	1.04%	1.00%
Volatility	49%	63%	47%	48%	60%	54%
Dividend yield	0	0	0	0	0	0
Expected life (years)	5.2	4.0	4.0	0.5	0.5	0.2
Resulting average fair value	$ 21.02	$ 18.83	$ 10.78	$ 10.86	$ 9.35	$ 4.53

During 2005, in preparation for the adoption of SFAS No. 123(R), the Company changed its method of estimating the expected volatility associated with stock option grants. Historically, the Company relied exclusively on the historical stock price changes (using daily pricing) and has since determined that a better estimate is used by taking an average of the historical stock price changes (using daily pricing) and the implied volatility on its traded options. Adopting this change has resulted in a decrease in the Company s

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weighted average volatility assumption from 63% in 2004 to 49% in 2005. Due to the Company s relatively short exercise history (commencing in May 2003), the expected term of options granted is estimated by using the Section 16 Insider reported data from a select group of peers whereas in previous years, the Company believed the vesting period approximated the expected life. Adopting this change has resulted in an increase in the Company s weighted average expected term assumption from 4.0 years in 2004 to 5.2 years in 2005. The risk-free interest rate is determined based upon a constant U.S Treasury Security with a contractual life that approximates the expected term of the option award.

Compensation cost is currently 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 will amortize all new grants straight-line over the vesting period. The Company plans to adopt the provisions of SFAS No. 123(R) using the modified prospective application, which provides for certain changes to the method for valuing share-based compensation. Under the modified prospective application, prior periods are not revised for comparative purposes. The valuation provisions of SFAS No. 123(R) apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. At December 31, 2005, unamortized compensation expense related to outstanding unvested options, as determined in accordance with SFAS No. 123, was approximately $30,000,000 before income taxes. In 2006, the Company will begin to record this unamortized amount as stock compensation expense pursuant to the vesting schedules of the underlying option awards. The Company will incur additional expense during 2006 related to new awards granted during 2006 that cannot yet be quantified.

Had compensation expense for stock options granted and issued ESPP purchase rights been determined based on their fair value at the date of grant, accounting consistent with SFAS No. 123, the Company s net income and net income per share would have been as follows (in thousands, except per share data):

	Years Ended December 31		
	2005	2004	2003
Net income:			
As reported	$ 60,089	$ 54,575	$ 35,330
Stock-based employee compensation expense included in reported net income, net of related tax effects	470	601	37
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(15,309)	(13,280)	(4,412)
Pro forma net income	$ 45,250	$ 41,896	$ 30,955
Net income per share:			
As reported			
Basic	$ 1.19	$ 1.10	$ 0.74
Diluted	$ 1.15	$ 1.06	$ 0.72
Pro forma			
Basic	$ 0.89	$ 0.85	$ 0.65
Diluted	$ 0.86	$ 0.82	$ 0.63

For the reasons noted below, certain adjustments were required to increase pro forma expenses for 2004 and 2003, resulting in a decrease of $2,311,000 and $1,320,000 to the adjusted pro forma net income, a

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decrease of $.04 and $.02 to the adjusted pro forma basic, and $.04 and $.03 to the adjusted pro forma diluted net income per share for the years ended December 31, 2004 and 2003, respectively.

During the year ended December 31, 2005, in conjunction with the Company s assessment of the impact of adopting SFAS No. 123(R), the Company determined that the pro forma expense related to actual forfeiture rates was computed incorrectly, as generated by a third party stock administration software. Further, the Company determined that it provided excess tax benefits on certain types of stock based compensation before they would have been realized as required by SFAS No. 123. As a result, the Company s pro forma compensation expense, adjusted for these two matters, is different than the amounts previously disclosed as follows (in thousands, except per share data):

	Three Months Ended			Years Ended December 31	
	September 30, 2005	June 30, 2005	March 31, 2005	2004	2003
As previously disclosed:					
Pro forma net income	$ 12,580	$ 9,247	$ 9,920	$ 44,207	$ 32,275
Pro forma diluted net income per share	$ 0.24	$ 0.18	$ 0.19	$ 0.86	$ 0.66
As revised:					
Pro forma net income	$ 12,578	$ 9,697	$ 9,588	$ 41,896	$ 30,955
Pro forma diluted net income per share	$ 0.24	$ 0.19	$ 0.18	$ 0.82	$ 0.63

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. Revenue from the Company s blood screening products shipped to countries where regulatory approval has been received is recorded as product sales based on a contracted transfer price with its third-party collaboration partner, Chiron Corporation (Chiron). Based on the terms of the Company s agreement with Chiron, the Company s ultimate share of the net revenue from sales to the end user is not known until reported by Chiron.

The Company manufactures its blood screening products according to Chiron s demand specifications and transfers completed product to Chiron s virtual warehouse, which is located on Gen-Probe s premises. Upon transfer to Chiron s virtual warehouse, the Company bills Chiron at an agreed upon transfer price, and Chiron remits payment within 30 days. In the past, the Company recorded all amounts billed as deferred revenue until shipment from the virtual warehouse to Chiron s end-customers or Chiron s international warehouse; upon which the Company then recognized blood screening product sales at the transfer price and recorded the related cost of products sold. The Company then adjusted blood screening product sales upon the Company s receipt of customer revenue reports and a net payment from Chiron of amounts reflecting its ultimate share of net sales by Chiron of these products, less the transfer price revenues previously paid.

During the year ended December 31, 2005, the Company s U.S. blood screening sales increased by approximately $5,358,000 due to the recognition of previously deferred revenue resulting from the shipment of Chiron controlled blood screening products from Chiron s virtual warehouse to Chiron s recently established third party warehouse, rather than directly to their end-customers.

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

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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 costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of an instrument, which ranges from three to five years; generally, three years for luminometers and DTS 400/800 instruments, and five years for TIGRIS and DTS 800/1600 instruments. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

The Company sells its instruments to Chiron for use in blood screening and records these instrument sales upon delivery since Chiron 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 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 agreement. 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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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 applicable to the blood screening development collaboration are reflected in the statements of income under the captions Research and development, Marketing and sales and General and administrative based on the nature of the costs. The costs incurred related to collaborative research revenue have exceeded the amounts recorded as revenue for all periods presented.

Shipping and handling expenses

Shipping and handling expenses are included in cost of product sales and totaled approximately $4,280,000, $2,569,000, and $2,258,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Contingencies

Contingent gains/losses are not recorded in the Company s financial statements since this accounting treatment could result in the recognition of gains/losses that might never be realized. The Company is currently involved in arbitration proceedings with Bayer Corporation (Bayer) concerning the parties collaboration for the development and sale of nucleic acid diagnostic tests for viral organisms. The Company received an arbitration award in tentative form in April 2005 and in interim form in June 2005. The arbitrator found, among other things, that Bayer is required to reimburse the Company $2,000,000 for the Company s legal fees and expenses related to the arbitration proceedings. The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration panel. Upon receipt of the final arbitration award and receipt of cash, if any, to reimburse the Company s legal fees and expenses, the Company expects to record the proceeds as a credit to expense either (i) within the general and administrative caption in the Company s statement of income where the legal fees and expenses were previously recorded or (ii) as a separate arbitration award operating expense line item.

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. At December 31, 2005 and 2004, capitalized patent costs, which have been included in License, manufacturing access fees and other assets on the consolidated balance sheet, totaled approximately $1,005,000 and $1,243,000, respectively, net of accumulated amortization. The Company expenses all costs related to abandoned patent applications.

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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $16,265,000, $14,497,000 and $14,380,000 for the years ended December 31, 2005, 2004 and 2003, 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 other purchased intangibles are amortized over their estimated useful lives. See Footnote 4 for further details of the Company s intangible assets and related amortization expense.

Impairment of long-lived assets

In accordance with SFAS No. 142, Goodwill and Other Intangible Assets, 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 2005 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, if indicators of impairment exist, the Company assesses the recoverability of the affected 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, 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, 2005.

Self-insurance reserves

The Company s consolidated balance sheets at December 31, 2005 and 2004 include approximately $1,816,000 and $1,402,000, 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 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.

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GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and development

Research and development costs are expensed as incurred.

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.

Recent accounting pronouncements

In December 2004, the FASB issued revised Statement No. 123 (SFAS No. 123(R)) Share-Based Payment, which requires companies to expense the estimated fair value of employee stock options and similar awards. Pro forma disclosure is no longer an alternative. In March 2005, the Securities and Exchange Commission (SEC) released SEC Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment. SAB No. 107 provides the SEC staff s position regarding the valuation of share-based payment arrangements for public companies. In April 2005, the SEC adopted a rule that effectively required the Company to implement SFAS No. 123(R) beginning on January 1, 2006.

As permitted by SFAS No. 123, Accounting for Stock-Based Compensation, the Company accounted through December 31, 2005, for share-based payments to employees using the intrinsic value method of Opinion No. 25 issued by the Accounting Principles Board (APB) and, as such, generally recognized no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123(R) s fair value method will have a significant impact on the Company s statements of income, although it is not expected to have an impact on the Company s overall financial position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in Note 1 to the consolidated financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current standards. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs an amendment of ARB 43, Chapter 4, which clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS No. 151 requires that those items be recognized as current-

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period charges regardless of whether they meet the criterion of so abnormal. In addition, it requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after July 15, 2005. The Company does not believe the adoption of this standard will have a material impact on its financial position or results of operations.

In December 2004, the FASB issued Staff Position No. SFAS 109-1, Application of Statement No. 109, Accounting for Income Taxes, for the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (SFAS No. 109-1). SFAS No. 109-1 clarifies that the deduction will be treated as a special deduction as described in SFAS No. 109, Accounting for Income Taxes. As such, the special deduction has no effect on deferred tax assets and liabilities existing at the date of enactment. The Company has estimated the current year impact of the deduction to be approximately $750,000 tax benefit, which has been reflected in its income tax expense for the year ended December 31, 2005.

Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share, and SAB No. 98. Under the provisions of SFAS No. 128, basic net income per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted average number of common and common equivalent shares outstanding during the period.

Each quarter, the Company reports the potential dilutive impact of stock options in its diluted earnings per common share using the treasury-stock method. Out-of-the-money stock options (i.e., the average stock price during the period is below the exercise price of the stock option) are not included in diluted earnings per share.

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

	December 31		
	2005	2004	2003
Net income	$ 60,089	$ 54,575	$ 35,330
Weighted average shares outstanding Basic	50,617	49,429	47,974
Effect of dilutive common stock options outstanding	1,828	1,974	1,163
Weighted average shares outstanding Diluted	52,445	51,403	49,137
Net income per share:			
Basic	$ 1.19	$ 1.10	$ 0.74
Diluted	$ 1.15	$ 1.06	$ 0.72

Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 210,995, 244,296 and 1,470,911 for the years ended December 31, 2005, 2004 and 2003, respectively were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

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2. Balance sheet information

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

Inventories

	December 31	
	2005	2004
Raw materials and supplies	$ 5,430	$ 5,345
Work in process	17,934	10,429
Finished goods	12,978	11,534
	$ 36,342	$ 27,308

Property, plant and equipment

	December 31	
	2005	2004
Land	$ 9,100	$ 9,100
Building	39,535	40,593
Machinery and equipment	106,433	93,337
Leasehold improvements	16,301	15,907
Furniture and fixtures	10,346	9,874
Construction in-progress	32,143	8,775
Property, plant and equipment (at cost)	213,858	177,586
Less accumulated depreciation and amortization	(108,668)	(100,935)
Property, plant and equipment (net)	$ 105,190	$ 76,651

License, manufacturing access fees and other assets

	December 31	
	2005	2004
Patents	$ 15,822	$ 15,305
Purchased intangible assets	33,636	33,636
License and manufacturing fees	48,126	22,026
Investment in Molecular Profiling Institute Inc.	2,500	
Other	228	236

	100,312	71,203
Less accumulated amortization	(50,664)	(46,808)
	$ 49,648	$ 24,395

As of December 31, 2005, the Company has capitalized $20,952,000, net in software costs associated with development of the TIGRIS instrument. In addition, the Company has an aggregate of $20,135,000 in TIGRIS-related items consisting of inventories, machinery and equipment and prepaid expenses.

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3. Short-term investments

The following is a summary of short-term investments as of December 31, 2005 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal securities	$ 184,713	$ 50	$ (1,466)	$ 183,297
Foreign debt securities	4,663			4,663
Total short-term investments	$ 189,376	$ 50	$ (1,466)	$ 187,960

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2005, by contractual maturity, are as follows (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Maturities				
Within one year	$ 63,773	$ 30	$ (307)	$ 63,496
After one year through five years	125,603	20	(1,159)	124,464
Total short-term investments	$ 189,376	$ 50	$ (1,466)	$ 187,960

The following table shows the gross unrealized losses and fair values of the Company s investments in individual securities that have been in a continuous unrealized loss position deemed to be temporary for less than 12 months and for more than 12 months, aggregated by investment category, as of December 31, 2005 (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Municipal securities	$ 118,603	$ (849)	$ 51,086	$ (617)
Foreign debt securities				
Total short-term investments	$ 118,603	$ (849)	$ 51,086	$ (617)

The following is a summary of short-term investments as of December 31, 2004 (in thousands):

	Gross Unrealized	Gross Unrealized	Estimated

	Cost	Gains	Losses	Fair Value
Municipal securities	$ 162,234	$ 391	$ (332)	$ 162,293
Corporate obligations	4,021		(5)	4,016
Mortgage backed government securities	2,035		(16)	2,019
Total short-term investments	$ 168,290	$ 391	$ (353)	$ 168,328

Gross realized gains from the sale of short-term investments were $95,000 and $402,000 for the years ended December 31, 2005 and 2004, respectively. Gross realized losses from the sale of short-term investments were $223,000 and $693,000 for the years ended December 31, 2005 and 2004. Realized gains and losses were not significant for the year ended December 31, 2003.

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4. Intangible assets by asset class and related accumulated amortization

The Company s intangible assets and related accumulated amortization consisted of the following (in thousands):

	December 31					
	2005			2004		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	$ 25,142	$ 4,190	$ 20,952	$ 25,142	$ 1,676	$ 23,466
Patents	15,822	14,817	1,005	15,305	14,062	1,243
Purchased intangible assets	33,636	32,330	1,306	33,636	31,994	1,642
License, manufacturing and other access fees	48,354	3,517	44,837	22,262	752	21,510
Total	$ 122,954	$ 54,854	$ 68,100	$ 96,345	$ 48,484	$ 47,861
Goodwill	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621
Investment in Molecular Profiling Institute Inc.	$ 2,500	$	$ 2,500	$	$	$

In January 2005, the Company entered into a license agreement with Corixa Corporation and received the right to develop molecular diagnostic tests for multiple potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancers. Pursuant to the terms of the agreement, the Company paid Corixa an initial access license fee of $1,600,000, an additional $1,600,000 in February 2006 and agreed to pay an additional $1,600,000 on January 31, 2007, unless the Company terminates the agreement prior to that date. The license fee has been recorded as an intangible asset which is being amortized on a straight-line basis to research and development expense over the life of the licensed patents, or 10 years.

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

In October 2005, the Company entered into a non-exclusive collaboration with Molecular Profiling Institute, Inc., a private company, to accelerate market development for the Company s pipeline of cancer diagnostics. Under the terms of the agreement, Molecular Profiling has agreed to validate, commercialize and undertake market development activities for up to four of the Company s products, starting with the Company s analyte specific reagents to detect

PCA3, a genetic marker for the detection of prostate cancer. In addition, in October 2005, the Company purchased from Molecular Profiling, an aggregate of 1,000,000 shares of Series B Preferred Stock, at a purchase price per share of $2.50. The Company has recorded its $2,500,000 investment on a cost basis, and will review the asset for impairment on an ongoing basis.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In November of 2005, 2004 and 2003, the Company paid $3,000,000, $1,000,000 and $3,000,000, respectively, to DiagnoCure related to Gen-Probe s exclusive license to DiagnoCure s PCA3 technology in the prostate cancer diagnostic market. These license fee payments have been recorded as an intangible asset which is being amortized on a straight-line basis to research and development over the remaining 12-year economic life of the patent(s).

The Company had aggregate amortization expense of $6,370,000, $3,717,000 and $1,442,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

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

Years Ended December 31		Amortization Expense
2006	$	5,854
2007		5,587
2008		5,424
2009		5,305
2010		4,925
Thereafter		20,777
Total	$	47,872

5. Long-term debt

The Company has an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2007, under which the Company may borrow up to $10,000,000, subject to a borrowing base formula, at the bank s prime rate, or at LIBOR plus 1.0%. At December 31, 2005, the Company did not have any amounts outstanding under the line and the Company has not taken advances against the line of credit since its inception. The Company was in compliance with all of the financial and restrictive covenants required by the line of credit agreement at December 31, 2005.

6. Related party transactions

During the year ended December 31, 2003, the Company recorded royalty expense to MLT of $1,451,000, prior to the Company s acquisition of a majority ownership interest in MLT in August 2003. All royalty expense incurred by the Company subsequent to the acquisition has been eliminated in the consolidated financial statements.

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7. Income taxes

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

	Years Ended December 31		
	2005	2004	2003
Current:			
Federal	$ 35,890	$ 22,499	$ 20,316
International	(103)	202	500
State	684	1,589	1,264
	36,471	24,290	22,080
Deferred:			
Federal	(5,798)	3,389	(3,443)
International	40	(114)	219
State	892	2,439	910
	(4,866)	5,714	(2,314)
	$ 31,605	$ 30,004	$ 19,766

The Company has not provided for United States income taxes on foreign subsidiaries undistributed earnings of approximately $2,500,000 at December 31, 2005, which are expected to be permanently reinvested outside the United States as these earnings have previously been taxed in the United States as Subpart F income.

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

	December 31	
	2005	2004
Deferred tax assets:		
Research and other tax credit carry-forwards	$ 4,576	$ 3,025
Inventory reserves and capitalization	6,679	5,075
Deferred revenue	1,963	2,238
Deferred compensation	987	132
Accrued vacation	1,849	1,716
Other accruals and reserves (net)	1,275	453
Total deferred tax assets	17,329	12,639
Valuation allowance	(319)	(1,243)
Total net deferred tax assets	17,010	11,396

Deferred tax liabilities:		
Other intangibles	(1,146)	(638)
Capitalized costs expensed for tax purposes	(8,534)	(8,927)
Depreciation	(2,065)	(3,293)
Total net deferred tax liabilities	(11,745)	(12,858)
Net deferred tax assets (liabilities)	$ 5,265	$ (1,462)

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Valuation allowances have been established for capital loss carry-forwards and credits for which the Company has determined it is more likely than not that these benefits will not be realized. The valuation allowance decreased during the year as credits were realized where previously there had been uncertainty regarding their realization.

At December 31, 2005, the Company also had California research and development credit carry-forwards of approximately $6,777,000, which do not expire. In accordance with the Internal Revenue Code (the Code) and applicable state rules, the Company s use of its credit carry-forwards could be limited in the event of certain cumulative changes in the Company s stock ownership.

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

	Years Ended December 31					
	2005	2004	2003	2005	2004	2003
Expected income tax provision at federal statutory rate	$ 32,096	$ 29,603	$ 19,305	35 %	35 %	35 %
State income tax provision, net of federal benefit	3,713	3,653	2,356	4 %	4 %	5 %
Federal tax credits	(635)	(1,500)	(1,500)	(1)%	(2)%	(3)%
State tax credits	(1,314)	(975)	(943)	(2)%	(1)%	(2)%
Other	(2,255)	(777)	548	(2)%	(1)%	1 %
Actual income tax provision	$ 31,605	$ 30,004	$ 19,766	34 %	35 %	36 %

Tax benefits of $8,677,000, $14,035,000 and $4,387,000 for the years ended December 31, 2005, 2004 and 2003, respectively, related to employee stock options and the Company s ESPP were credited to stockholders equity.

8. Stockholders equity

In May 2004, the Company s stockholders approved an increase in the authorized number of shares of common stock under the Company s Certificate of Incorporation from 100,000,000 to 200,000,000 shares.

In September 2002, the Company adopted a stockholder rights plan that could discourage, delay or prevent an acquisition of the Company under certain circumstances. The rights plan was amended by the Board of Directors in November 2003. The rights plan provides for preferred stock purchase rights attached to each share of the Company s common stock, which will cause substantial dilution to a person or group acquiring 15% or more of the Company s stock if the acquisition is not approved by the Company s Board of Directors. In connection with the rights plan, the Company declared a dividend of one preferred share purchase right for each outstanding share of common stock of the Company, which automatically adjusted to one-half of a right as a result of the 100% stock dividend paid by the Company in September 2003. Under the terms of the rights plan, the rights would become exercisable on the tenth day following the acquisition by a person or group of 15% or more of Gen-Probe s common stock, or commencement of a tender offer for Gen-Probe s common stock that would result in the ownership of 15% or more of the Company s common stock by one person or group. Each right will initially represent the right, under certain circumstances, to purchase 1/100 of a share of newly created Series A Junior Participating Preferred Stock of the Company at an exercise price of $300. The exercise price is subject to adjustment by the Company. The Board of Directors may terminate the rights plan or redeem the rights at the redemption price of $0.01 per right, subject to adjustment, at any time prior to the earlier of September 26, 2012, the expiration date of the rights, or the date of distribution of the rights, as determined under the rights plan. The rights plan has a term of 10 years. The

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initial distribution of rights is expected to be non-dilutive and non-taxable to stockholders for United States federal income tax purposes.

Stock options

The Company adopted the 2003 Plan in May 2003 that provides for the issuance of up to 5,000,000 shares of common stock for grants under the 2003 Plan. The 2003 Plan provides for incentives for officers, directors, employees and consultants through the granting of incentive and non-statutory stock options, restricted stock and stock appreciation rights. The exercise price of each option granted under the 2003 Plan must be equal to or greater than the fair market value of the Company s stock on the date of grant. The Board of Directors may determine the terms and vesting of all options and other awards granted under the 2003 Plan; however, in no event will the option term exceed 10 years. Generally, options granted under the 2003 Plan will vest at the rate of 25% or 33% one year from the grant date and 1/48 or 1/36, respectively, each month thereafter until the options are fully vested.

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

The Company adopted the 2000 Equity Participation Plan (the 2000 Plan) in August 2000 that provides for the issuance of up to 4,827,946 shares of common stock for grants under the 2000 Plan. The 2000 Plan provides for the grant of incentive and non-statutory stock options. The exercise price of each option granted under the 2000 Plan must be equal to or greater than the fair market value of the Company s stock on the date of grant. The Board of Directors may determine the terms and vesting of all options; however, in no event will the contractual term exceed 10 years. Generally, options vest 25% or 33% one year from the grant date and 1/48 or 1/36, respectively, each month thereafter until the options are fully vested.

A summary of the Company s stock option activity for all Plans is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2002	4,678,092	$ 12.93
Granted	2,043,932	27.19
Exercised	(1,083,238)	13.20
Cancelled	(166,266)	16.34
Outstanding at December 31, 2003	5,472,520	18.10
Granted	2,061,329	37.21
Exercised	(1,178,052)	14.15
Cancelled	(351,743)	24.97
Outstanding at December 31, 2004	6,004,054	25.03
Granted	1,227,700	43.82
Exercised	(890,134)	17.65
Cancelled	(388,034)	32.78
Outstanding at December 31, 2005	5,953,586	$ 29.53

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In addition, the Company had 60,000 shares of Deferred Issuance Restricted Stock Awards and 112,000 shares of restricted stock outstanding as of December 31, 2005 that have not been reflected in the table above.

The following table summarizes information about stock options outstanding at December 31, 2005:

	Options Outstanding			Options Exercisable	
	Shares Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Shares Exercisable	Weighted Average Exercise Price
Range of Exercise Prices					
$ 6.75 - $12.29	943,767	6.3	$ 11.81	779,583	$ 11.76
$13.50 - $15.51	827,428	5.1	13.72	790,465	13.69
$19.19 - $29.53	1,120,158	7.6	28.42	629,996	28.23
$30.68 - $36.47	448,996	7.9	34.14	175,771	33.68
$36.59	1,018,237	8.7	36.59	303,632	36.59
$37.42 - $42.50	1,023,191	9.3	41.56	170,362	40.70
$43.55 - $50.91	571,809	9.3	46.10	90,241	44.11
	5,953,586	7.7	$ 29.53	2,940,050	$ 22.35

Shares of common stock available for future grants under all stock option plans were 940,420 at December 31, 2005.

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

	Years Ended December 31		
	2005	2004	2003
Exercise price equal to the fair value of common stock on the grant date:			
Weighted-average exercise price	$ 43.82	$ 37.21	$ 27.19
Weighted-average option fair value	$ 21.02	$ 18.83	$ 10.78
Exercise price greater than fair value of common stock on the grant date:			
Weighted-average exercise price	$	$	$
Weighted-average option fair value	$	$	$

Employee stock purchase plan

In May 2003, the Company adopted, and the Company s stockholders subsequently approved, the ESPP that provides for the issuance of up to 1,000,000 shares of the Company s common stock, as adjusted to reflect the 100% stock dividend paid by the Company in September 2003. The ESPP is intended to qualify under Section 423 of the Code and is for the benefit of qualifying employees as designated by the Board of Directors. Under the terms of the

ESPP, purchases are made semiannually. Participating employees may elect to have a maximum of 15% of their compensation, up to a maximum of $10,625 per six month period, withheld through payroll deductions to purchase shares of common stock under the ESPP. The purchase price of the common stock purchased under the ESPP is equal to 85% of the fair market value of the common stock on the offering

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or Grant Date or the exercise or purchase date, whichever is lower. During the years ended December 31, 2005, 2004 and 2003, employees purchased 96,779, 132,218 and 34,714 shares at an average price of $30.87, $28.49 and $16.91 per share, respectively. As of December 31, 2005, 736,289 shares were reserved for future issuances under the ESPP.

9. Commitments and contingencies

Lease commitments

The Company leases certain facilities under operating leases which expire at various dates through August 31, 2009.

Future minimum payments under operating leases as of December 31, 2005 are as follows (in thousands):

2006	$ 2,065
2007	863
2008	167
2009	70
Total payments	$ 3,165

Rent expense was $2,938,000, $2,626,000 and $1,700,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Collaborative agreements

Effective May 2, 1997, the Company entered into agreements which created a worldwide relationship between Gen-Probe and bioMérieux Vitek, Inc. (bMx). The collaboration involved research and development activities, as well as the transfer to bMx of product distribution rights in international markets, excluding Japan. As part of the agreements, Gen-Probe licensed its probe-related technology to bMx to jointly develop probe assays and adapt and develop instrumentation during a five-year and ten-year term. In August 2000, the bMx agreement was amended to transition the relationship from a collaborative arrangement to two royalty bearing license agreements with certain performance obligations. In September 2004, the Company entered into a termination agreement with bMx which terminated one of the August 2000 license agreements. In connection with the termination agreement, the Company recorded net revenue of $100,000 during the year ended December 31, 2004.

In September 2004, at the same time it entered into the termination agreement, the Company signed non-exclusive licensing agreements with bMx and its affiliates that provide bMx s affiliates options to access the Company s ribosomal RNA technologies for certain uses. Under the terms of the agreements, bMx s affiliates paid the Company $250,000 in 2004 for limited non-exclusive research licenses and options to develop diagnostic products for certain targets using the Company s patented ribosomal RNA technologies. In January 2005, bMx s affiliates exercised the first of these options and paid $4,500,000 to the Company, pursuant to the terms of the agreement. In December 2005, bMx s affiliates exercised a second option for additional targets and paid the Company $2,100,000. During the year ended December 31, 2005, the Company recorded $3,877,000 of these cumulative payments as license fee revenue, based on the total number of targets selected and the total number of targets that may be selected by the end of 2006. By the end of 2006, bMx s affiliates may acquire rights to develop products for additional targets by paying the Company up to an additional $900,000, depending on the number of additional targets, if any, selected by bMx s affiliates. Further, the Company will receive royalties on the sale of any products developed by bMx s affiliates using the Company s intellectual property.

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On February 3, 2006, bioMérieux terminated the second of the two August 2000 license agreements. Upon payment of minimum royalties for 2006 in the amount of $500,000, bMx will not have any further obligations under the terminated license. Termination of the second August 2000 license does not affect the September 2004 licenses.

In June 1998, the Company entered into an agreement with Chiron to form a strategic alliance to develop, manufacture and market nucleic acid probe assay systems for blood screening and certain areas of clinical diagnostics. Under the terms of the agreement, Chiron or a third party will market and sell products that utilize Chiron s intellectual property relating to hepatitis C virus (HCV) and human immunodeficiency virus (type 1)(HIV-1) and the Company s patented technologies. The Company received an up-front license fee of $10,000,000 from Chiron in 1998, which the Company recorded as deferred revenue and is being recognized as license revenue over a 10-year term. In September 1998, Chiron assigned the clinical diagnostic portion of the agreement to Bayer. The Company recorded licensing revenues of approximately $670,000 from Chiron for each of the years ended December 31, 2005, 2004 and 2003, respectively, related to this aspect of the agreement. In January 2004, the Company began United States clinical trials of the Procleix Ultrio assay on the fully automated, high-throughput TIGRIS instrument systems triggering a $6,500,000 contract milestone payment under the agreement which the Company recorded as license revenue. The Company may receive an additional $10,000,000 contract milestone payment upon FDA approval of the Procleix Ultrio assay on the TIGRIS instrument.

Since June 2003, U.S. blood centers have used the Procleix West Nile virus (WNV) assay to screen more than 29 million units of donated blood under an Investigational New Drug (IND) application. The Company submitted a Biologics License Application (BLA) for the WNV assay to the FDA in February 2005. The Company does not separately track the costs applicable to the blood screening development collaboration with Chiron and therefore is not able to quantify the direct costs associated with the collaborative research revenue. The Company believes that the costs incurred related to the collaborative research revenue have exceeded the amounts recorded as revenue in all periods presented. For the years ended December 31, 2005, 2004 and 2003, the Company recognized $18,369,000, $18,543,000 and $5,962,000, respectively, in collaborative research revenue through its collaboration with Chiron from deliveries of WNV tests on a cost recovery basis. The Company has developed a NAT assay to detect WNV, which is currently being used in clinical trials under an IND application. For the years ended December 31, 2005 and 2004, the Company recognized $1,972,000 and $1,421,000, respectively in reimbursements for expenses incurred for WNV development research as collaborative research revenue. In early 2006, the Company expects to discontinue recognizing these sales as collaborative research revenue upon first shipment of FDA approved and labeled product.

The Company is currently developing the Procleix Ultrio assay, a nucleic acid test (NAT) assay to detect HIV-1, HCV and hepatitis B virus (HBV), in donated human blood. Gen-Probe develops these assays through its collaboration with Chiron. In March 2003, the Company signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. During the years ended December 31, 2005, 2004 and 2003, the Company received $2,759,000, $2,766,000 and $3,932,000, respectively, in reimbursements for expenses incurred related to the development of the Procleix Ultrio assay from Chiron.

With respect to the Company s collaboration with Chiron, both parties have obligations to each other. The Company is obligated to manufacture and supply its blood screening assay to Chiron, and Chiron 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 Chiron intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

In connection with the joint development of the Procleix HIV-1/ HCV assay, and as a condition for Chiron s agreement to pay for most of the clinical trial costs related to approval of that assay, the Company

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agreed to pay the costs related to the clinical trial for the next joint development project with Chiron. The obligation of Gen-Probe was limited to the cost incurred for the previous joint clinical trial, which was approximately $4,100,000. During the year ended December 31, 2004, the Company satisfied this obligation and began to bill Chiron for its share of qualifying clinical trial expenses for the eSAS Ultrio and WNV projects in accordance with their agreement.

In August 2005, the Company entered into a collaboration agreement with Millipore Corporation (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, the Company will be primarily responsible for assay development and manufacturing, while Millipore will manage worldwide commercialization of any products resulting from the collaboration.

In July 2005, the Company entered into a collaboration agreement with GE Infrastructure Water and Process Technologies (GEI), a unit of General Electric Company, 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, the Company will be primarily responsible for assay development and manufacturing, while GEI will manage worldwide commercialization of any products resulting from the collaboration.

License agreements

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

Effective January 1, 2004, the Company entered into agreements with Tosoh Corporation to cross-license intellectual property covering certain NAT technologies. The licenses cover products in clinical diagnostics and other related fields. Under the agreements, Tosoh received non-exclusive rights to the Company s proprietary Transcription-Mediated Amplification (TMA), and rRNA technologies in exchange for two payments during 2004 totalling $7,000,000, which was recognized as revenue in the first quarter of 2004 as there were no additional obligations placed on the Company after the effective date of the contract and the transfer of the technology. Additionally, Tosoh will pay the Company royalties on worldwide sales of any future products that employ Gen-Probe s technologies licensed by Tosoh. The Company will gain access, in exchange for the payment of royalties, to Tosoh s patented Transcription Reverse-Transcription Concerted (TRC), amplification and Intercalation Activating Fluorescence detection technologies for use with the Company s real time TMA technology.

Government contract

In October 2002, the Company received a $1,000,000 cost sharing contract with the National Institutes of Health (NIH) to develop a NAT assay for the detection of the WNV. In February 2003, this amount was increased by $2,470,000 and the Company filed for an IND covering the WNV. In November 2003, the Company received $4,300,000 of supplemental contract funding from the NIH. This contract extension supported the Company s pursuit of clinical studies and submission of a BLA for the Company s NAT for the detection of WNV in donated human blood. The Company initiated the development of this assay and has recognized collaborative research revenue under the contract extension as reimbursable costs were incurred. Under these NIH WNV contracts, the Company recorded revenue totaling $2,952,000 and $4,817,000 for the

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years ended December 31, 2004 and 2003, respectively. As of July 2004, the Company had billed and collected all monies under this contract.

Litigation

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

Enzo Biochem, Inc.

In June 1999, the Company was sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that the Company and other defendants have willfully infringed United States patent no. 4,900,659, or the 659 patent, through the manufacture and sale of products for the diagnosis of gonorrhea. On July 27, 2004, the District Court granted summary judgment in favor of the Company and other defendants, and against Enzo, holding that the 659 patent is invalid based on the on-sale doctrine. On September 30, 2005, the United States Court of Appeals for the Federal Circuit affirmed the judgment in the Company s favor. Enzo did not file for rehearing with the Federal Circuit or petition the U.S. Supreme Court for a writ of certiorari within the time allowed. The Company believes that this matter is now concluded.

Bayer Corporation

In November 2002, the Company filed a demand for arbitration against Bayer in the Judicial Arbitration & Mediation Services, Inc. (JAMS), office in San Diego, California related to the Company s collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. Under the terms of the June 1998 collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of human immunodeficiency virus (HIV), hepatitis viruses and other specified viruses, subject to certain conditions. Gen-Probe s demand for arbitration stated that Bayer failed to fulfill the conditions required to maintain exclusive distribution rights. The arbitration demand sought confirmation that the agreement grants Gen-Probe, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC was also added as a respondent and counterclaimant. The hearing on the matter began on September 13, 2004 and closing arguments were completed on November 3, 2004.

On April 5, 2005, the arbitrator issued a Tentative Opinion and Award, and requested comments be submitted from the parties related to implementation of the decision. After considering and incorporating some of the parties suggestions, on June 24, 2005, the arbitrator issued an Interim Opinion and Award. The Interim Opinion and Award adopted all substantive rulings of the Tentative Opinion and Award. The arbitrator determined that the Company is entitled to a co-exclusive right to distribute qualitative TMA assays to detect HCV and HIV-1 for the remaining term of the agreement. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as the Company requested. As a result of a termination of the agreement, the Company will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Bayer also will be required to reimburse the Company $2,000,000 for the Company s legal fees and expenses related to the

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arbitration proceedings. As discussed in Note 1 Summary of significant accounting policies (Contingencies), the Company will not record any award for reimbursement of legal fees and expenses until the arbitration has been finalized and the cash has been received.

The arbitrator rejected Bayer s multimillion-dollar counterclaim for damages. In the June 2005 Interim Opinion and Award, the arbitrator also concluded that an additional hearing would be required to determine whether a royalty payment would be required as a result of the Company exercising its co-exclusive rights to distribute the qualitative TMA assays for HCV and HIV-1, and, if so, the amount and beneficiary of such royalties. The additional hearing took place on September 14 and 15, 2005. On March 3, 2006, the arbitrator issued his Tentative Award following the additional hearing. The arbitrator concluded that Gen-Probe is licensed under the relevant HIV and HCV patents for qualitative assays during the term of the collaboration agreement and that the Company is not obligated to pay Bayer an initial license fee in connection with the sale of those assays. The arbitrator further concluded that the Company will be required to pay running sales royalties to Bayer on the Company s sales of the qualitative TMA assays for HCV and HIV-1. The Company believes the royalty rates are generally consistent with rates paid by other licensees of the relevant patents. The March 3, 2006 Tentative Award is subject to revision by the arbitrator following comments by the parties.

The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within JAMS. There can be no assurances as to the final outcome of the arbitration.

A separate patent infringement action that the Company filed in March 2004 against Bayer remains pending in the United States District Court for the Southern District of California. This action alleges that Bayer s bDNA nucleic acid tests for HIV and HCV infringe Gen-Probe s U.S. patent no. 5,955,261, entitled Method for Detecting the Presence of Group-Specific Viral mRNA in a Sample, or the 261 patent. Bayer s bDNA tests are not covered by the collaboration agreement between the companies. Bayer has denied the allegations of infringement and alleged that the 261 patent is invalid or unenforceable. On August 10, 2005, the Company subsequently amended its complaint to further allege that Bayer s HIV and HCV bDNA tests also infringe Gen-Probe s U.S. patent no. 5,424,413, entitled Branched Nucleic Acid Probes and Gen-Probe s U.S. patent no. 5,451,503, entitled Method for Use of Branched Nucleic Acid Probes. On August 23, 2005, Gen-Probe filed a second patent infringement action against Bayer, alleging that Bayer s bDNA nucleic acid test for HBV infringes the 261 patent and further alleging that Bayer s bDNA nucleic acid test for HCV infringes Gen-Probe s U.S. patent no. 5,030,557, entitled Means and Method for Enhancing Nucleic Acid Hybridization Assays.

No trial date has been set for either patent infringement case. There can be no assurances as to the final outcome of the litigation.

On October 4, 2005, Bayer filed a demand for arbitration against the Company with the JAMS office in San Francisco, California related to the Company s collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. At the same time, Bayer filed a civil lawsuit against the Company in Superior Court of Massachusetts for Middlesex County. In both the demand for arbitration and the complaint, Bayer alleges that the Company is developing real-time diagnostic assays for HIV and HCV that are covered by certain patents, without the authorization of the patent owner. The subject patents were issued to Chiron and licensed non-exclusively to Bayer. On October 17, 2005, the Company removed the state court suit to federal court in Boston. On October 21, 2005, Bayer moved to remand the case to the Massachusetts state court. On October 27, 2005, the Company filed a motion to dismiss the case. Both motions are under submission for decision by the court. The Company intends to vigorously defend Bayer s allegations. However, there can be no assurance that these matters will be resolved in the Company s favor.

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Other

The Company is obligated to purchase TIGRIS instruments and raw materials used in manufacturing from two key vendors. The minimum combined purchase commitment was approximately $22,582,000 for the year ended December 31, 2005. Of the $14,420,000 in TIGRIS instruments expected to be purchased, the Company anticipates that approximately $9,333,000 will be reimbursed by Chiron.

10. Significant customers and geographic information

During the years ended December 31, 2005, 2004 and 2003, 52%, 47% and 42%, respectively, of net revenues were from one customer. No other customer accounted for more than 10% of revenues in any fiscal year.

During the years ended December 31, 2005, 2004 and 2003, 48%, 43% and 41%, respectively, of product sales were from the sale of commercially approved blood screening products. Other revenues related to the development of blood screening products prior to commercial approval are recorded in collaborative research revenue as disclosed in Note 9, Commitments and contingencies (Collaborative agreements). During the years ended December 31, 2005, 2004 and 2003, 52%, 57% and 59%, respectively, of product sales were from the sale of clinical diagnostic products and instruments.

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

	Years Ended December 31		
	2005	2004	2003
Total revenue:			
North America	$ 236,474	$ 224,607	$ 180,924
Rest of World	69,491	45,100	26,267
	$ 305,965	$ 269,707	$ 207,191

11. Employee benefit plan

Effective May 1, 1990, Gen-Probe established a Defined Contribution Plan (the Plan) covering substantially all employees of Gen-Probe beginning the month after they are hired. Employees may contribute up to 20% of their compensation per year (subject to a maximum limit imposed by federal tax law). Gen-Probe is obligated to make matching contributions each payroll equal to a maximum of 50% of the first 6% of compensation contributed by the employee. The contributions charged to operations related to Gen-Probe employees totaled $1,384,000, $1,332,000 and $1,110,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

12. Deferred compensation plan

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

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GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

defined in the Plan. Certain key participants must wait six months following termination of employment to receive distributions. The Plan is subject to Section 409A of the Code.

The Company may terminate the Plan at any time with respect to participants providing services to the Company. Upon termination of the Plan, participants will be paid out in accordance with their prior distribution elections and otherwise in accordance with the Plan. Upon and for twelve (12) months following a change of control, the Company has the right to terminate the Plan and, notwithstanding any elections made by participants, to pay out all benefits in a lump sum, subject to the provisions of the Code. As of December 31, 2005, the Company had approximately $557,000 of accrued deferred compensation and these amounts have been classified as accrued salaries and employee benefits on the face of the balance sheet.

13. Quarterly information (unaudited)

The following tables set forth the quarterly results of operations for each quarter within the two-year period ended December 31, 2005 (in thousands, except per share data). The information for each of these quarters is unaudited and has been prepared on the same basis as the Company s audited financial statements. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited quarterly results when read in conjunction with the Company s audited financial statements and related notes. The operating results of any quarter are not necessarily indicative of results for any future period.

	Quarter Ended			
	March 31	June 30	September 30	December 31
2005				
Total product sales	$ 59,579	$ 65,131	$ 68,941	$ 77,999
Total revenues	68,828	72,894	76,271	87,972
Cost of product sales	15,498	20,350	21,399	26,653
Total operating expenses	48,798	52,922	54,282	62,996
Net income	13,461	13,456	16,417	16,755
Net income per share:				
Basic	$ 0.27	$ 0.27	$ 0.32	$ 0.33
Diluted	$ 0.26	$ 0.26	$ 0.31	$ 0.32

	Quarter Ended			
	March 31	June 30	September 30	December 31
2004				
Total product sales	$ 55,030	$ 52,600	$ 56,447	$ 58,483
Total revenues	76,486	61,225	63,487	68,509
Cost of product sales	13,864	13,164	15,272	17,608
Total operating expenses	46,378	43,114	46,544	51,173
Net income	19,728	11,761	11,110	11,976
Net income per share:				
Basic	$ 0.40	$ 0.24	$ 0.22	$ 0.24
Diluted	$ 0.39	$ 0.23	$ 0.22	$ 0.23

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SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS
For The Three Years Ended December 31, 2005
(In thousands)

	Balance at Beginning of Period	Addition Charged to Cost and Expenses	Deductions[1]	Balance at End of Period
Allowance for doubtful accounts:				
Year Ended December 31, 2005:	$ 664	$ 207	$ (81)	$ 790
Year Ended December 31, 2004:	$ 717	$	$ (53)	$ 664
Year Ended December 31, 2003:	$ 787	$ (48)	$ (22)	$ 717
Inventory reserves:				
Year Ended December 31, 2005:	$ 6,579	$ 2,480	$ (2,884)	$ 6,175
Year Ended December 31, 2004:	$ 7,307	$ 5,506	$ (6,234)	$ 6,579
Year Ended December 31, 2003:	$ 10,969	$ 5,487	$ (9,149)	$ 7,307

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

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

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INDEX TO EXHIBITS

Exhibit Number	Description
2.1(3)	Separation and Distribution Agreement, dated and effective as of May 24, 2002, and amended and restated as of August 6, 2002, by and between Chugai Pharmaceutical Co., Ltd. and Gen-Probe Incorporated.
3.1(3)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(14)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(3)	Form of Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(14)	Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(3)	Specimen common stock certificate.
4.2(5)	Rights Agreement, dated as of September 16, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C.
4.3(6)	First Amendment to Rights Agreement, dated October 9, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC.
4.4(11)	Second Amendment to Rights Agreement, dated November 20, 2003.
10.1(2)	Transition Services Agreement, dated April 4, 2002, by and between Chugai Pharma USA, LLC and Gen-Probe Incorporated.
10.2(4)	Form of Tax Sharing Agreement between Chugai Pharma USA, LLC and Gen-Probe Incorporated.
10.3(13)	The 2000 Equity Participation Plan of Gen-Probe Incorporated.
10.4(15)	The 2000 Equity Participation Plan Form of Agreement and Grant Notices.
10.5(13)	The 2002 New Hire Stock Option Plan.
10.6(15)	The 2002 New Hire Stock Option Plan Form of Agreement and Grant Notice.
10.7(13)	The 2003 Incentive Award Plan of Gen-Probe Incorporated.
10.8(15)	The 2003 Incentive Award Plan Form of Agreement and Grant Notice.
10.9(15)	The 2003 Incentive Award Plan Form of Restricted Stock Award Agreement and Grant Notice.
10.10(10)	Amendment No. 1 to the 2003 Incentive Award Plan of Gen-Probe Incorporated.
10.11(14)	Employee Stock Purchase Plan.
10.12(4)	Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*
10.13(4)	Addendum dated June 11, 1998 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*
10.14(4)	Amendment dated December 7, 1999 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.
10.15(1)	Amendment No. 2 dated February 1, 2000 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.
10.16(4)	Amendment No. 3 effective April 1, 2002 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*
10.17(9)	Amendment No. 4 effective March 5, 2003 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.

10.18(12)	Amendment No. 5 effective January 1, 2004 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.
10.19(12)	Future Blood Screening Assay Ultrio Addendum effective January 1, 2001 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*
10.20(12)	Future Blood Screening Assay West Nile Virus Addendum effective June 1, 2003 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*

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Exhibit Number	Description
10.21(1)	Supplemental Agreement dated April 2, 2001 to the Agreement dated June 11, 1998 for Development, Distribution and Licensing of TMA Products between Gen-Probe Incorporated and Bayer.*
10.22(4)	Amended and Restated ANAIS License, Development and Cooperation Agreement entered into as of August 4, 2000 between Gen-Probe Incorporated and bioMérieux, Inc.*
10.23(4)	Amended and Restated VIDAS License, Development and Cooperation Agreement entered into as of August 4, 2000 between Gen-Probe Incorporated and bioMérieux, Inc.*
10.24(1)	Distribution Agreement entered into May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.25(4)	Distributorship Arrangements Agreement entered into May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.26(1)	Renewal Amendment entered into November 2, 1999 to the Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.
10.27(1)	First Amendment entered into August 4, 2000 to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 between Gen-Probe Incorporated and bioMérieux S.A.*
10.28(14)	2003 Amendment to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997, entered into May 2, 2003 by and between Gen-Probe Incorporated and bioMérieux, S.A.*
10.29(15)	Ribosomal Nucleic Acid License and Option Agreement (for Easy Q Instrument) dated September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux B.V.*
10.30(15)	Guarantee Agreement dated September 30, 2004 by bioMérieux SA, on behalf of its subsidiary bioMérieux, Inc. in favor of Gen-Probe Incorporated.
10.31(15)	Ribosomal Nucleic Acid License and Option Agreement (for GeneXpert Instrument) dated September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux, Inc.*
10.32(15)	Guarantee Agreement dated September 30, 2004, by bioMérieux SA, on behalf of its subsidiary bioMérieux b.v. in favor of Gen-Probe Incorporated.
10.33(15)	Side Letter dated October 1, 2004 by and between Gen-Probe Incorporated, bioMérieux B.V., and bioMérieux, Inc.*
10.34(15)	License Agreement entered into September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux B.V.*
10.35(15)	Vidas Termination Agreement entered into September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux, Inc.*
10.36(4)	License Agreement effective as of July 1, 2001 between Gen-Probe Incorporated and Rebio Gen, Inc. (as successor-in-interest to Chugai Diagnostics Science Co., Ltd.).*
10.37(4)	Distribution Agreement effective as of September 1, 1998 between Gen-Probe Incorporated and Rebio Gen, Inc. (as successor-in-interest to Chugai Diagnostics Science Co., Ltd.).*
10.38(4)	First Amendment effective June 30, 2002 to September 1, 1998 Distribution Agreement between Gen-Probe Incorporated and Rebio Gen, Inc. (as successor-in-interest to Chugai Diagnostics Science Co., Ltd.).*
10.39(4)	Co-Exclusive Agreement effective as of April 23, 1997 between Gen-Probe Incorporated and The Board of Trustees of the Leland Stanford Junior University.*
10.40(1)	Amendment No. 1 effective April, 1998 to the License Agreement effective April 23, 1997 between Stanford University and Gen-Probe Incorporated.*

10.41(4)	Non-Assertion Agreement effective as of February 7, 1997 between Gen-Probe Incorporated and Organon Teknika B.V.*
10.42(12)	Agreement effective as of July 12, 1984 between the Welsh National School of Medicine and Bioanalysis Limited.*
10.43(12)	Agreement effective July 12, 1990 between University of Wales College of Medicine and Molecular Light Technology Limited.*
10.44(4)	License Agreement effective as of January 21, 1986 among Gen-Probe Incorporated, Bioanalysis, Ltd. And the University of Wales College of Medicine.*

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Exhibit Number	Description
10.45(4)	Amendment entered into as of May 11, 1989 to the License Agreement effective as of January 21, 1986 among Gen-Probe Incorporated, Bioanalysis, Ltd. and the University of Wales College of Medicine.*
10.46(4)	Amendment entered into as of November 19, 1998 to the License Agreement effective as of January 21, 1986 among Gen-Probe Incorporated, Bioanalysis, Ltd. and the University of Wales College of Medicine.*
10.47(4)	Third Amendment entered into as of February 19, 2002 to the License Agreement effective as of January 21, 1986 among Gen-Probe Incorporated, Bioanalysis, Ltd. And the University of Wales College of Medicine.*
10.48(12)	Amendment Agreement entered into as of July 8, 2003 related to Certain Licence Agreements between the University of Wales College of Medicine, Bioanalysis Limited and Gen-Probe Incorporated.
10.49(4)	Non-exclusive License Agreement dated June 22, 1999 between Gen-Probe Incorporated and Vysis, Inc.*
10.50(15)	Settlement Agreement entered into September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc.*
10.51(15)	Amendment to Nonexclusive License Agreement under Vysis Collins Patents entered into September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc.*
10.52(4)	Amended and Restated License Agreement dated June 19, 2002 between Gen-Probe Incorporated and The Public Health Research Institute of The City of New York, Inc.*
10.53(4)	Development, License and Supply Agreement entered into as of October 16, 2000 between Gen-Probe Incorporated and KMC Systems, Inc.*
10.54(1)	First Amendment made as of September, 2001 to Agreement entered into as of October 16, 2000 between Gen-Probe Incorporated and KMC Systems, Inc.*
10.55(1)	Contract effective as of January 1, 2000 between Gen-Probe Incorporated and the National Institutes of Health (No. N01-HB-07148).
10.56(12)	Modification No. 9 effective as of November 5, 2003 to the Contract effective as of January 1, 2000 between Gen-Probe Incorporated and the National Institutes of Health (No. N01-HB-07148)
10.57(4)	Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.58(1)	First Amendment effective as of February 12, 2001 between Gen-Probe Incorporated and Roche Diagnostics GmbH, the successor-in-interest to Boehringer Mannheim GmbH, to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.59(16)	Second Amendment effective as of August 31, 2004 between Gen-Probe Incorporated and Roche Diagnostics, the successor-in-interest to Boehringer Mannheim GmbH, to the Supply Agreement effective as of March 5, 1998 between Gen-Probe Incorporated and Boehringer Mannheim GmbH.*
10.60(12)	License, Development and Cooperation Agreement between Gen-Probe Incorporated and DiagnoCure Inc. effective as of November 19, 2003.*
10.61(12)	Target License Agreement between Tosoh Corporation and Gen-Probe Incorporated effective as of January 1, 2004.*
10.62(12)	TRC License Agreement between Tosoh Corporation and Gen-Probe Incorporated effective as of January 1, 2004.*

10.63(12)	TMA License Agreement between Tosoh Corporation and Gen-Probe Incorporated effective as of January 1, 2004.*
10.64(14)	Supply Agreement entered into January 1, 2002 by and between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.65(14)	Supply Agreement Amendment Number One entered into June 4, 2004 by and between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.66(16)	License Agreement between AdnaGen AG and Gen-Probe Incorporated effective as of December 30, 2004.*

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Exhibit Number	Description
10.67(16)	License Agreement between Corixa Corporation and Gen-Probe Incorporated effective as of December 31, 2004.*
10.68(3)	Credit Agreement dated April 10, 2001, by and between Gen-Probe Incorporated, Gen-Probe Sales & Service, Inc. and Wells Fargo Bank, National Association.
10.69(3)	First Amendment dated June 10, 2002 to Credit Agreement dated April 10, 2001 by and between Gen-Probe Incorporated, Gen-Probe Sales & Service, Inc. and Wells Fargo Bank, National Association.
10.70(3)	Revolving Line of Credit Note dated July 1, 2002 made by Gen-Probe Incorporated and Gen-Probe Sales & Service, Inc. in favor of Wells Fargo Bank, National Association.
10.71(2)	Promissory Note dated September 29, 2000 by Niall M. Conway and Margaret Conway.
10.72(3)	Form of Indemnification Agreement between Gen-Probe Incorporated and its Executive Officers and Directors.
10.73(9)	Employment Agreement dated as of April 2, 2003 between Gen-Probe Incorporated and Henry L. Nordhoff.
10.74(12)	First Amendment to Employment Agreement effective as of January 1, 2004 between Gen-Probe Incorporated and Henry L. Nordhoff.
10.75(15)	Deferred Issuance Restricted Stock Conversion Agreement, Deferred Issuance Award Agreement and Election Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated October 8, 2004.
10.76	Form of Employment Agreement Executive Team.
10.77	Form of Employment Agreement Vice Presidents.
10.78(8)	Gen-Probe Incorporated Change-In-Control Severance Compensation Plan for Employees.
10.79 (17)	Modified Blood Screening Instrument eSAS 2 Addendum effective January 1, 2002 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*
10.80 (17)	Amendment No. 6 effective January 1, 2004 to Agreement dated as of June 11, 1998 between Gen- Probe Incorporation and Chiron Corporation.*
10.81(17)	Supply and Purchase Agreement between Gen-Probe Incorporated, F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc. effective February 15, 2005.*
10.82(17)	Amendment dated February 1, 2005 to Deferred Issuance Restricted Stock Conversion Agreement, Deferred Issuance Award Agreement and Election Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated October 8, 2004.
10.83 (18)	Employment Offer Letter, dated July 15, 2005, between Gen-Probe Incorporated and Stephen J. Kondor.
10.84 (19)	Gen-Probe Incorporated Deferred Compensation Plan effective as of June 30, 2005.
10.85 (19)	Deferred Issuance Restricted Stock Award Grant Notice and Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated May 20, 2005.
10.86 (20)	2003 Incentive Award Plan Form of Restricted Stock Award Agreement and Grant Notice, as amended.
10.87 (21)	Letter Agreement between Gen-Probe Incorporated and Chiron Corporation, dated June 11, 1998.**
21.1	List of subsidiaries of Gen-Probe Incorporated.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification dated March 10, 2006, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2	Certification dated March 10, 2006, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification dated March 10, 2006, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification dated March 10, 2006, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

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Filed herewith.

Indicates management contract or compensatory plan, contract or arrangement.

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

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

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

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

(5) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on September 17, 2002.

(6) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q filed with the SEC on November 14, 2002.

(7) Intentionally omitted.

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

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

(10) Incorporated by reference to Gen-Probe s Report on Form S-8 filed with the SEC on May 29, 2003

(11) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on November 21, 2003.

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

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

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

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

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

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

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

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

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

(21) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on December 8, 2005.
* Gen-Probe has been granted confidential treatment with respect to certain portions of this exhibit.
** Gen-Probe has requested confidential treatment with respect to certain portions of this exhibit.