GEN PROBE INC
Form 10-K
March 15, 2005

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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, 2004

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: 0-21872
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 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes þ No o

As of June 30, 2004, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $2.3 billion, based on the closing price of the registrant s common stock on the Nasdaq National Market on June 30, 2004 of $47.32 per share.

As of March 1, 2005, 50,402,454 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™, GEN-PROBE®, LEADER®, PACE®, TIGRIS®, TMA™ 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 endorsements 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 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 1. Business 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.

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. 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. Our FDA-approved human immunodeficiency virus (type 1), or HIV-1, assay, hepatitis C virus, or HCV, assay, and our investigational test for West Nile virus, our Procleix WNV assay, are currently utilized to screen over 80% of the United States donated blood supply for HIV-1, HCV and WNV. In addition, our TIGRIS DTS instrument, or 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

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in the United States and is approved in Europe for use 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 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 49 representatives. Our blood screening products are marketed and distributed by Chiron Corporation, or Chiron. In addition, we have agreements with Bayer, bioMérieux and Fujirebio, through its subsidiary Rebio Gen, Inc., to market some of our products in various global markets. 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 have achieved a leading position in the industry because of our technologically advanced and reliable NAT assays and instruments and 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 worked with outside vendors to develop a range of instrument systems to perform our assays.

We have developed what we believe to be the world s first fully automated, integrated, high-throughput, NAT instrument system, the TIGRIS instrument. We believe the TIGRIS instrument significantly reduces labor costs and contamination risks in high-volume diagnostic testing environments and also enables large blood collection centers to individually test donors blood. The TIGRIS instrument is intended initially for clinical diagnostic applications. 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. 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 instrument system, received its Conformite Europeene, or CE, mark which permitted Chiron to launch the product in the European Economic Area. We filed a Biologics License Application, or BLA, for our Procleix Ultrio assay for use on our semi-automated Procleix system and our TIGRIS instrument, with the FDA in the third quarter of 2004. The TIGRIS instrument, and our Procleix Ultrio assay for use on the TIGRIS instrument, received CE marks in December 2004. We filed a BLA with the FDA for our Procleix WNV assay in January 2005 for use on our TIGRIS instrument and our semi-automated instrument platform.

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.

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.

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

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

The attraction of a nucleotide sequence to its complementary sequence 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 double strands. 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 probe that is designed to bind specifically to a 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, probe has bound to sequences from the target organism.

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 in 2004, was approximately $1.9 billion. While NAT represents only a small portion of the estimated $28 billion worldwide IVD market, it is the fastest growing segment. Boston Biomedical Consultants, Inc.,

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reported that the worldwide NAT market grew approximately 17% from 2003 to 2004. We focus our business on market opportunities in two principal segments of the NAT market, clinical diagnostics and blood screening. The clinical diagnostic market currently accounts for the majority of our NAT sales. According to Sannes and Associates, Inc., our products represented approximately 53% of the total chlamydia and gonorrhea tests sold in the United States in 2004. In addition, according to a January 2004 survey by the Centers for Disease Control and Prevention, or CDC, our sales represented approximately 75% of the United States amplified tuberculosis testing market at that time. We also are exploring opportunities to develop products to address emerging segments of the NAT market. 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 2.8 million new cases in the United States each year according to the CDC. The clinical consequences of undiagnosed and untreated chlamydia infections include pelvic inflammatory disease, ectopic pregnancy and

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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. Currently, most of the testing for chlamydia and gonorrhea occurs in the United States.

Tuberculosis, or TB, the disease caused by the microorganism *Mycobacterium tuberculosis*, remains one of the deadliest diseases in the world. The World Health Organization, or WHO, estimates that each year there are more than eight million new cases of tuberculosis worldwide and approximately two million people die from the disease. 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. Quantitative tests are useful in monitoring the efficacy of treatments to reduce the amount of virus in circulation. NAT assays currently are used to detect viruses such as HIV, HCV and HBV.

HIV is the virus responsible for acquired immune deficiency syndrome, or AIDS. In 2003, there were approximately 930,000 reported cases of AIDS in the United States, according to the CDC. 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. In addition, 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.

The CDC estimates that almost 73,000 additional people in the United States are infected with HBV each year. Chronic HBV infection can lead to the development of severe, potentially fatal complications, such as cirrhosis of the liver.

Blood Screening. We believe the field of blood screening is one of the fastest growing areas for NAT assays. According to WHO, approximately 80 million units of blood are drawn annually 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 are HIV, HCV and HBV. There is also growing concern over the presence of other viruses in the donated blood supply, including WNV, parvo B19 and hepatitis A virus, or HAV. 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 HIV or HCV 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 of our customers, 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 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. Consequently, if the donor has not developed detectable antibodies or detectable

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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 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 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 effective means of accomplishing individual donor testing, or IDT, with HBV is using our TIGRIS instrument. IDT on our TIGRIS instrument was recently 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. Target 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 many potential carriers of STDs forego diagnosis due to the current 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. We believe expansion of the screening of these populations will be accelerated by adoption of guidelines by the Health Plan Employer Data and Information Set, or HEDIS, an organization that provides information about, and recommendations to, managed health care organizations, that call for routine screening of certain populations, such as women between the ages of 16 and 25, to improve early detection and treatment of chlamydia.

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 viral 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.

Additionally, we believe there will be significant demand for automation if blood collection centers begin the screening of individual blood donations, rather than the current widespread practice of testing of pooled samples, in an effort to further improve the safety of the nation s blood supply. Individual unit screening at larger blood centers currently is impractical without automated instrumentation because of the throughput limitations of current semi-automated instruments. We believe that the availability of automation will encourage adoption of additional blood screening tests, such as tests for HBV and WNV.

Responsiveness to newly emerging threats. We believe that our ability to respond rapidly to the emergence of new infectious diseases, such as WNV, will contribute to the growth of our blood screening and diagnostic businesses. Our platform of generic reagents and assay formats allows us to rapidly develop new assays for our blood screening or diagnostic businesses as soon as we know the genetic sequence of a new organism.

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

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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 2004, some blood centers used our technology and assays, under an investigational exemption, for individual unit testing. Approximately 1200 infected units have been intercepted using our WNV assay since July of 2003.

Growth in viral load testing. We expect increased monitoring of patients on antiviral therapies to contribute to the growth in the market for NAT products. Antiviral therapies are managed by periodic measurement of the concentration of virus present in the blood, or the viral load. Monitoring the viral load can be used to determine when therapy is appropriate, to monitor the course of therapy and to determine the optimal time for a change in therapy. NAT tests can also provide additional information useful in managing patients with these viral infections, including identification of subtypes that are known to be resistant to certain antiviral agents or that are associated with different responses to certain treatments. The primary viral infections for which viral monitoring is useful include those caused by HIV, HCV and HBV. Nucleic acid viral load tests for HIV have been widely adopted by clinical laboratories over the past seven years, but we expect market growth in the short-term because of the introduction of new therapies and increased testing worldwide. In addition, we expect increases in monitoring for HCV in connection with the emergence of new antiviral therapies for HCV. Numerous research programs exist today in anti-viral therapy, with novel anti-viral therapeutics in development that have the potential to produce additional diagnostic opportunities. As these therapies are developed and marketed, we expect a corresponding increase in demand for NAT products to monitor the efficacy of these therapies.

Development of emerging markets for NAT technology. We believe markets will continue to develop for new applications for NAT technology in both clinical and non-clinical fields. Among clinical fields, we believe NAT technology will be utilized in the areas of new analytes, such as cancer diagnosis, 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.

New markers to detect the presence of cancer cells in tumors 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 and our license agreement with Corixa Corporation, or Corixa, could represent an innovative application of our NAT technology to detect genetic markers in urine for prostate cancer. These markers are called PCA3 (DD3) and AMACR, respectively.

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.

Emerging non-clinical markets for NAT include water, food, beverage, bioterrorism, pharmaceutical manufacturing, personal care products manufacturing and environmental 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 this new market.

Improvements in Detection Technologies. Current amplified nucleic acid tests generally provide an end point result, requiring that the amplification and detection processes are completed before a result is obtained. New technology now in development is likely to permit kinetic or real time detection of target

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analytes as amplification proceeds, permitting conclusions to be drawn before the amplification process is complete, and thereby reducing the time to an end point result. Real time detection methods also offer the advantage of providing both a qualitative and quantitative result from a single test.

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 arrays of core NAT technologies in the industry. Our products incorporate these technologies, which, in combination, have significantly advanced NAT assays, making them more specific, more sensitive, easier to use and faster 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 sensitivity, less risk of contamination and greater ease of use than our competitors amplification products. We believe our target capture technology, which is used to extract specific target sequences from a complex clinical specimen, can remove inhibitory substances that interfere with amplification, can be easily automated, and can be performed in an extremely short duration of time. 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 tuberculosis 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 emerging segments of the NAT market.

Extensive Product and Intellectual Property Portfolio

We believe that we are unique in offering our customers a broad portfolio of both non-amplified and amplified NAT assays, as well as multiple instrumentation platforms on which to perform our NAT 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 is currently utilized to screen over 80% of the United States donated blood supply for HIV-1 and HCV. Prior to FDA approval, our Procleix HIV-1/ HCV assay was used pursuant to IND protocols. In 2004, we conducted clinical testing in United States blood centers of our WNV assay to detect the virus in freshly donated human blood. 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. Our products and technologies are covered by 390 United States and foreign patents, 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 January 31, 2005, our world-class research and development group consisted of more than 225 employees, 92 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, our scientists have developed proprietary assays that have brought significant innovation to the market for NAT clinical diagnostics. 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 what we believe to be the world s first fully automated, integrated, high-throughput, NAT instrument system, known as the TIGRIS instrument. Our current initiatives to expand our position in clinical diagnostics and blood screening while applying our core NAT technologies to cancer detection, genetic testing pharmacogenomics 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.

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Brand Recognition

We believe that we benefit from significant brand name recognition and customer loyalty among laboratories 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 2004 were to repeat customers. We believe that our brand name also facilitates market acceptance of our new products, providing us with opportunities for growth. Since 1998, the American Red Cross has used us as its sole source for NAT assays for blood screening, which is an example of our standing in the industry.

Sales and Technical Support Capabilities

As of January 31, 2005, our direct sales force consisted of approximately 31 representatives and an 18-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 15 years of overall sales experience, with an average of six 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 approximately 99 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 ISO 9001 and EN 13485 certification from the TUV, a global leader in independent testing and assessment services. We believe our expertise in regulatory, clinical and quality assurance and our manufacturing facilities enables 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 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 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 a number of areas, including chlamydia, gonorrhea and tuberculosis testing. Our ability to strategically identify and assume leadership roles in new markets was evidenced by our entrance into the blood screening market. We successfully developed the first FDA-approved NAT assay for HIV-1/ HCV detection, our Procleix HIV-1/ HCV assay, which is currently used to screen over 80% of the United States donated blood supply. Our WNV assay, which is available for use by United States blood centers for investigational clinical testing of the virus in freshly donated human blood, also is currently being used to screen more than 80% of the United States blood supply. We developed the WNV assay for use in conjunction with our TIGRIS instrument to enable high volume IDT in the blood screening market. 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

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cleared for commercial distribution in Europe. We currently are exploring opportunities and expect to develop new products for emerging NAT markets. We developed our first cancer-related product, a TMA-based assay for the detection of chronic myelogenous leukemia, or CML, and commercialized it in Japan. Our license and collaboration agreements with DiagnoCure and Corixa could represent an innovative application of our NAT technology to detect new, highly specific genetic markers for prostate cancer. In the industrial market, we developed a NAT assay for *Listeria monocytogenes*, a food pathogen, that is used by the dairy industry in Europe, and a NAT assay for mycoplasma that is used by tissue culture facilities to detect contamination of cell lines. We also are evaluating additional product opportunities in genetics, pharmacogenomics, food and industrial testing.

Deliver Proprietary Automated and Fully Integrated Systems for NAT Assays

We will continue to develop instruments that complement our established product lines in clinical diagnostics and blood screening. 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. Ultimately, we believe this approach of providing our customers with the latest generation of systems solutions will allow us to sustain and reinforce our market position and brand recognition.

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

We will 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, our APTIMA Combo 2 assay, which was launched in August 2001, integrates over 20 of our proprietary technologies. 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 went into some of our prior products. We believe that this approach and our experience in bringing FDA-approved products to market will reduce development cycle times for new products. This, 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 to new technologies and disease markers, as these markers are discovered and clinically validated by third parties. For example, in 2003, we acquired a majority of the outstanding shares of Molecular Light Technology Limited and its subsidiaries, providing us with a base for operations in Europe. We also 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 November 2004, we signed an exclusive option agreement with Qualigen, Inc. to develop a point-of-use NAT testing platform using Qualigen s FDA-approved FastPack® technology. In December 2004, we entered into a license agreement with AdnaGen AG, or AdnaGen, under which we received an exclusive license to AdnaGen technology that may help increase the accuracy of molecular diagnostic tests for prostate and other cancers. In addition, in December 2004 we entered into a license

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agreement with Corixa Corporation pursuant to which we received rights to approximately 50 potential genetic markers in the areas of prostate, ovarian, kidney, lung, colon and other cancers.

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 Chiron s patent portfolio relating to HCV and to leverage Chiron s distribution and sales resources.

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 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, and

chemiluminescent detection using Hybridization Protection Assay and Dual Kinetic Assay technologies.

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 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. Because of our patented rRNA technology, we are the only company able to offer convenient and sensitive non-amplified NAT assays for the detection of non-viral microorganisms in the United States.

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.

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

Target Capture/ Nucleic Acid Extraction Technology. Detection of target organisms that are present in small numbers in a large-volume clinical sample requires that target organisms be concentrated to a detectable level. One way to accomplish this is to isolate the particular nucleic acid of interest by binding it to a solid support, which allows the support, with the target bound to it, to be 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 from the reaction tube. We use these techniques in conjunction with our patented amplification methods in our current generation of amplified assays. 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 acids 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.

Some 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 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 the many problems faced with 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 produces 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 expensive thermocyclers required by PCR. All reagents are added to the tube and nothing is removed. This

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makes the test simpler to use and suitable for automation, and it minimizes the possibility of carry-over contamination and false positive test results;

TMA is very robust and often can be used with clinical samples with little or no purification;

The RNA nucleic acid that is synthesized in the TMA reaction is much more labile when outside the reaction tube and in the lab environment than the DNA that is produced in the PCR method. This reduces the possibility of carry-over contamination;

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

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

Chemiluminescent Technologies and Hybridization Protection Assay. Our current DNA probes use chemiluminescent acridinium esters, or AE molecules, that generate light as a label for detection. The AE technology is much more sensitive than fluorescence or absorbance techniques used by our competitors. 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 unbound probes, leaving the label on the bound probes unaffected. When the light off reagent is added to the specimen tube, 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 tube or microtiter plate 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.

APTIMA Technology. We have combined target capture, TMA and DKA together into an integrated family of technologies known as APTIMA. APTIMA assays represent the latest generation of nucleic acid amplification testing, 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. 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 rRNA from culture isolate by 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	*Chlamydia trachomatis* and *Neisseria*	PACE December 1987 PACE 2 April	Gen-Probe North

	sample by Hybridization Protection Assay	*gonorrhoeae*, including combined detection	1992 PACE 2C October 1994		America bioMérieux, Rebio Gen and other distributors Rest of World
Mycobacterium Tuberculosis Direct Test (or MTD)	Transcription-Mediated Amplification of rRNA in patient sample and detection by Hybridization Protection Assay	*Mycobacterium tuberculosis*	December 1995		Gen-Probe North America bioMérieux, Rebio Gen and other distributors Rest of World

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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 ASR, APTIMA GC ASR	Target Capture, Transcription-Mediated Amplification of rRNA and detection by Dual Kinetic Assay	*Chlamydia trachomatis* and *Neisseria gonorrhoeae*	Not required	Gen-Probe	U.S.
APTIMA CT APTIMA GC			December 2004 March 2005	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. In 2004, our STD products accounted for approximately 53% of the United States markets for chlamydia and gonorrhea testing. Our NAT assays have proven to be more sensitive and specific than traditional enzyme immunoassay methods. The PACE 2 System currently is the major clinical diagnostic product line we manufacture and sell. Our PACE 2C is 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 detect and confirm both chlamydia infections and gonorrhea. The PACE product family also includes the PACE Specimen Collection kits for endocervical and urethral specimens. Sales of our PACE family of assays accounted for 20% of our total revenues in 2004, 29% of our total revenues in 2003 and 44% of our total revenues in 2002. The decrease in the percentage of total revenues represented by our PACE family of assays is attributable to two factors. First, our total revenues are increasing primarily due to increases 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 customers over to our amplified APTIMA Combo 2 product line which, while partially decreasing PACE family revenues, ultimately contributes to total clinical diagnostic product sales growth.

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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 amplified MTD assay was initially approved by the FDA in December 1995. Additional applications of the test were subsequently approved. 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 have 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 adequate 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 piercable cap that eliminates the need to uncap samples prior to testing and a sample transport medium that preserves the integrity of the sample for weeks at room temperature. We also believe it currently is the only NAT assay that can be used to accurately screen urine samples for chlamydia infections and gonorrhea with the same sensitivity as seen from cervical and urethral samples.

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 in all segments of 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.

We have completed clinical trials to evaluate APTIMA Combo 2 to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from Cytyc Corporation s liquid Pap transport media. 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. Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from the liquid Pap medium would offer patients, physicians and laboratories convenient testing for several diseases from one sample, and further differentiate what we believe to be the superior performance of APTIMA Combo 2 in the widest range of specimen types. We filed for United States regulatory clearance of the Cytyc application in 2004. Additionally, we are currently evaluating initial clinical data from the TriPath liquid Pap transport media.

APTIMA CT ASR, APTIMA GC ASR, APTIMA CT and APTIMA GC. We also have developed individual analyte specific reagents, or ASRs, to separately detect the presence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. 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

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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. Our APTIMA CT assay was granted marketing clearance by the FDA in December 2004 and our APTIMA GC assay was granted marketing clearance by the FDA in March 2005.

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 viral 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. Our viral diagnostic assays currently are run on our semi-automated instruments incorporating components of our DTS system. Our principal products for viral diagnostics include our qualitative HCV Test and our ASR for quantitative HCV testing, as set forth below.

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 have 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. Our ASR for Quantitative HCV currently is provided by Bayer to Quest Diagnostics Incorporated, a leading national diagnostics company. If we determine that there is sufficient demand for this test, we will consider the development of a FDA-approved product in the future.

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. Our principal blood screening products are set forth below.

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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 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 Europe
Procleix WNV Assay	Target Capture, Transcription- Mediated Amplification of viral RNAs, detection by Dual Kinetic Assay	WNV in donated blood	Not approved	Chiron U.S. under IND

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 world. The Red Cross provides almost half of the nation s entire blood supply of 14 million units by working with more than 4.5 million donors and 3,000 hospitals through its 38 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, approximately 99% of the nation s blood supply is being screened with NAT and over 80% of this screening is being done with the Gen-Probe/ Chiron Procleix HIV-1/ HCV assay. The Procleix HIV-1/ HCV assays supplied under the IND were delivered on a cost recovery basis.

Testing by these organizations under the IND started in June 1999 and pivotal clinical trials were completed in 2000. The completion of these trials allowed us to submit a BLA to the FDA for the Procleix HIV-1/ HCV assay, which the FDA-approved 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 system, which currently is performed on a version of our DTS instrumentation, provides sufficient throughput for screening pooled samples of donor blood. However, we believe that the FDA will ultimately require testing of each unit of blood individually.

Testing each unit 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 the adoption of individual donor testing.

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. In December 2003, we commenced clinical trials of the Procleix Ultrio assay in the United States. 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

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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 up to 42% over 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 January 2004, we commenced clinical trials of the Procleix Ultrio assay in the United States on our TIGRIS instrument. 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 the semi-automated Procleix system and on the fully-automated TIGRIS instrument. 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 Union, as well as in other parts of the world that accept the CE mark.

In June 2003, we announced that our WNV assay was available for use by United States blood centers to begin clinical testing of the virus in freshly donated human blood. The WNV assay currently is being used to screen over 80% of the United States blood supply. The test is being distributed by Chiron and is the first such test to prospectively screen the United States blood supply under an IND. The prospective protocol was accepted by the FDA in May 2003. The development of the WNV assay was partially funded by the National Heart, Lung and Blood Institute of the NIH. We filed a BLA for the WNV assay with the FDA in January 2005. As of December 31, 2004, the assay had tested over 19 million donations and intercepted approximately 1200 WNV-infected blood donations through ongoing national screening under an IND. In addition, the TIGRIS instrument was used by several blood centers in 2004 to screen both individual donor and pooled blood donations for WNV under an IND, the first such instance of IDT for a high volume NAT test being performed on a fully automated instrument.

Emerging Diagnostic Applications

We believe that our NAT technology and our instrumentation are well suited for numerous emerging applications. We developed our first cancer-related product, a TMA-based assay for the detection of chronic myelogenous leukemia, or CML, that has been approved in Japan. We also entered into a license and collaboration agreement with DiagnoCure to apply our NAT technology in the detection of a new, highly specific genetic market for prostate cancer. The successful transfer of DiagnoCure s first-generation technology for prostate cancer detection to our APTIMA technology platform was completed in the first half of 2004. We believe that the sensitivity and specificity provided by our technologies will allow us to develop additional products that can be used for detecting and monitoring the expression of genes associated with cancer. In addition, we have licensed 46 potential markers for genitourinary and other cancers from Corixa, including a gene called AMACR, that we believe is the second most promising marker for a molecular-based prostate cancer diagnostic test. We have also licensed innovative cell capture technology from AdnaGen that may allow for enhancing the concentration of target prostate cancer cells, thereby further increasing the sensitivity and specificity of disease detection.

In the industrial market, we developed a NAT assay to detect the bacterium *Listeria monocytogenes* from a cultured sample. We received FDA approval for this product in June 1990. *Listeria* is a food pathogen, and our assay is used by the dairy industry in Europe to monitor for *Listeria* contamination. We also developed a test for mycoplasma that is used by tissue culture facilities in the industrial and research markets to detect contamination of cell lines and culture media. We are currently evaluating additional product opportunities in the pharmaceutical manufacturing, personal care product manufacturing, beverage, environmental, food and water testing.

In addition, we are evaluating the feasibility of our technology to detect genetic markers that might be useful as indicators of a patient s predisposition to some disease states and also in the prediction of a patient s responsiveness to a particular therapy. We are also evaluating the market for potential products in these areas.

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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 begun to implement multi-year sales contracts that have an equipment factor set forth in them. By placing our proprietary instrumentation systems 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 systems 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 4,000 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 Instrument Systems

Laboratories need nucleic acid testing solutions that are accurate, efficient and economical. To meet this demand, we have developed the family of DTS Systems. The DTS family of systems 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 instrument systems 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 instrument system is a fully-integrated modular system that includes 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 system adds 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 system, which was formerly known as eSAS, for use in blood screening under the Procleix trademark. The version of the DTS system that Chiron markets has received FDA approval and foreign governmental approval in the countries where our blood screening products are sold. Bayer markets systems comprised of components of the DTS system for HCV clinical diagnostic assays. The systems that Bayer markets do not require FDA or foreign governmental approval.

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TIGRIS DTS Instrument System

We have developed the TIGRIS DTS instrument system, or TIGRIS instrument, which we believe is the first high-throughput instrument to completely 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.

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 Procleix WNV TIGRIS 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. We believe the TIGRIS instrument will be utilized in clinical diagnostic laboratories and blood banks throughout the world. We capitalized $25.1 million of costs 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 certain STDs on the TIGRIS instrument. In the United States, the TIGRIS instrument is able to be used in clinical diagnostic applications to perform NAT assays that have been previously cleared by the FDA following clinical trials on our existing instrumentation.

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 the semi-automated Procleix system and on the fully automated TIGRIS instrument. The Procleix Ultrio assay received its CE mark in January 2004 for use on our semi-automated Procleix system. In October 2004, we submitted to European regulators a design dossier amendment for use of the Procleix Ultrio assay on the TIGRIS instrument. In December 2004, we received a CE mark for the TIGRIS instrument for use with the previously CE marked 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.

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. As of January 31, 2005, our direct sales force consisted of a staff of approximately 31 sales representatives. We also support our sales efforts through a staff of 18 field technical representatives. Our sales representatives average over 15 years of selling experience, with an average of six years focused on sales of NAT products. Sales representatives principally focus on large accounts including large reference laboratories, public health laboratories and hospitals throughout the United States and generally do not focus on physicians at this time. We continually educate our sales representatives on the technical, clinical and economic merits of our products. We use sales meetings, technical on-line sales training and in-the-field training to ensure our sales representatives are properly informed about all areas of our product lines and selling processes. Our blood screening products are marketed and distributed by 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

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various national and regional 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 market opportunities, provide diagnostic solutions to address unmet customer needs, and to provide comprehensive after-sale product support. In addition, our field technical support group provides thorough 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.

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 47% of our total revenues in the year ended December 31, 2004 and 42% of our total revenues for the year ended December 31, 2003. 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 for the year ended December 31, 2004. 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 for the year ended December 31, 2004 and 21% of our total revenues for the year ended December 31, 2003. Although state and city public health agencies are legally independent of each other, 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 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 among the parties.

Under the agreement, our share of revenues from the initial Procleix HIV-1/ HCV assay ranged from 43% to 47.5% through 2003. 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. For commercial assays that do not test

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for HCV, such as the prospective West Nile test, 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. From inception through December 31, 2004, we recognized a total of $318 million in revenue under this collaboration agreement and have recorded $5.7 million in deferred license revenues as of December 31, 2004.

The collaboration agreement has an initial term of 10 years from the first commercial sale of blood screening assays, which occurred in the first 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 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 three months ended March 31, 2004. During January 2004, the Procleix Ultrio assay, running on our semi-automated instrument system, received its CE mark, which permitted Chiron to launch the product in the European Union. 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.

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 NAT assays for viral targets and cancer markers in the clinical diagnostic market with Bayer. Pursuant to the collaboration, we and Bayer initially developed and are manufacturing and marketing quantitative and qualitative assays for HCV. In the event that any third-party technology is needed to continue development under our collaboration agreement with Bayer, costs for obtaining such third-party technology will be allocated among 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, 2004, we recognized a total of $10.6 million in revenue under our collaboration agreement with Bayer, including $1.9 million in revenue during the year ended December 31, 2004.

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

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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 the 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 and other specified viruses, subject to certain conditions. In the arbitration, we are seeking to prove that Bayer has failed to fulfill the conditions required to maintain its exclusive distribution rights. Accordingly, we are seeking confirmation that the agreement grants us, 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 monetary damages based on alleged delays in the development of the TIGRIS instrument and certain assays, and other claims. The hearing on the matter began on September 13, 2004 and closing arguments were completed on November 3, 2004. The arbitrator agreed to review additional written testimony following closing arguments, and has informed the parties that he intends to issue a written decision on or about March 25, 2005. There can be no assurances as to the final outcome of the arbitration.

National Institutes of Health Contracts

In January 2000, we began work on a three-year $13.4 million cost sharing contract with the NIH to modify the Procleix HIV-1/ HCV assay to incorporate HBV detection capability and make it simpler for organ donation centers to test the blood of organ donors. Through December 31, 2002, the NIH had reimbursed us $7.8 million of these costs or 100% of the cost-sharing portion for which they were responsible. We and Chiron will share equally the remaining costs to complete the project.

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 December 31, 2004, we recognized $18.2 million in sales revenue under this distribution agreement, including $2.6 million in sales revenue during the year ended December 31, 2004. The distribution agreement with Rebio Gen terminates on December 31, 2005. Prior to that date, 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.

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.

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In August 2000, we entered into amended agreements with bioMérieux, Inc. that transitioned the relationship from a collaborative arrangement to a royalty-bearing arrangement that covered semi-automated probe assays and advanced fully-automated, probe assays for the diagnosis of infectious diseases and detection of food pathogens. In September 2004, we entered into a termination agreement with bioMérieux, which effectively terminated the 1997 collaborative research agreements and the amended agreements that we entered into with bioMérieux in August 2000. Pursuant to the terms of the termination agreement, bioMérieux paid us an aggregate of approximately $1.6 million to conclude certain outstanding royalty and other obligations under the terminated agreements. 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. Through December 31, 2004, we recognized a total of $50.3 million in revenue under the agreements, including $4.8 million during the year ended December 31, 2004.

In September 2004, we also entered into non-exclusive licensing agreements with bioMérieux and its affiliates that provide bioMérieux and its 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 paid us an aggregate of $250,000 for two limited non-exclusive, non-transferable, without the right to grant sublicenses except to affiliates, research licenses and two non-exclusive, non-transferable options for licenses to develop diagnostic products for certain disease targets using our patented ribosomal RNA technologies. These options were exercised by bioMérieux s payment to us of $4.5 million in January 2005. bioMérieux may also acquire rights to develop products for additional targets, if any, by paying us up to an additional $3.0 million, the exact total additional amount based on the number of additional targets, if any, selected by bioMérieux, by the end of 2006. Under each license, we will receive royalties from bioMérieux on the net sale of any products bioMérieux develops using our intellectual property. If any option is exercised, the resulting license agreement shall 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, we have the right to terminate these agreements, and the respective licenses granted to bioMérieux thereunder, upon 60 days prior written notice to bioMérieux delivered within six (6) months of the date of such 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. Through December 31, 2004, we have not recognized any revenue under these agreements.

License Agreement with Rebio Gen. In July 2001, we entered into a license agreement with Chugai Diagnostics Science Co., Ltd., a subsidiary of our parent corporation at that time. As noted above, 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, 2004, we have recognized a total of $2.8 million in revenue under this agreement, including $0.3 million in revenue during the year ended December 31, 2004. 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 products 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,

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2004, we have recognized a total of $3.4 million in revenue under this agreement, including $0.7 million in revenue during the year ended December 31, 2004. 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. In 2004, we recognized a total of $7.0 million in revenue under these agreements.

Licenses We Have Obtained to Third-Party Technology that We Use in Our Products

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, 2004, we incurred a total of $2.8 million in expenses under this agreement, including $1.2 million in expenses during the year ended December 31, 2004. Our obligation to make royalty payments under this agreement terminates when the patents constituting the Stanford amplification technology expire, which is expected to occur in July 2017. This agreement may be terminated by Stanford upon a material breach of the agreement by us that is not cured following 60 days written notice.

Non-Assertion Agreement with Organon Teknika B.V. In February 1997, we entered into a non-assertion agreement with Organon Teknika. Both parties possessed certain rights regarding transcription-based amplification methods. The agreement allows both parties to practice their respective amplification methods with immunity from legal action from the other party for actually or allegedly infringing each other s patent rights. The agreement terminates upon the expiration of the last of the patent rights that are subject to the agreement, which is expected to occur in February 2016. 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. We do not believe the merger will have a material effect on the bioMérieux license or the Organon Teknika non-assertion agreement.

License from University of Wales College of Medicine. Our consolidated 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 chemiluminescence technology for use in NAT assays. In 1986, we entered into an agreement with UWCM pursuant to which we obtained an exclusive sublicense to the technology. 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. Our 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. We paid royalties to UWCM totaling $2.2 million and $0.8 million for the years ended December 31, 2004 and 2003, respectively. The agreement with UWCM may also be terminated by either party upon breach of the agreement that is not cured following specified notice provision.

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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 are obligated to make royalty payments to Vysis based on sales of products incorporating the licensed technology. From inception through December 31, 2004, we incurred a total of $9.2 million in expenses under this agreement, including $3.5 million in 2004. The agreement terminates upon the expiration of the last of the patent rights that are subject to this agreement, which is expected to occur in July 2015. This agreement may be terminated by Vysis upon breach of the agreement by us that is not cured. The agreement may be terminated by us on written notice to Vysis. In December 2001, Vysis was acquired by Abbott Laboratories, Inc., one of our principal competitors.

In December 1999, we initiated litigation in which we sought a declaratory judgment that our products were not covered by the Vysis patents that are the subject of the above license and that the patents are invalid and unenforceable. The case was submitted to trial by jury in May 2002, and the jury returned alternative verdicts in favor of Gen-Probe, finding the subject patents do not cover Gen-Probe s products and that they are invalid on the grounds of obviousness and lack of enablement. Following post-trial motions, judgment was entered on August 5, 2002 in our favor. Vysis appealed the judgment and has obtained amended patent claims from the Patent and Trademark Office. In October 2002, we filed a second lawsuit to challenge the scope and validity of the reissued patent. On March 5, 2004, the appeals court vacated the prior judgment in our favor and directed the District Court to dismiss the case, on the ground of lack of subject matter jurisdiction. In September 2004, we entered into a settlement agreement and an amendment to our non-exclusive license agreement with Vysis under which we agreed to withdraw our patent litigation against Vysis and agreed to pay Vysis an aggregate of $22.5 million. This aggregate amount included $20.5 million for a fully paid up license to eliminate all future royalty obligations by us 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. 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 paid by us to Vysis on 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, 2004, we incurred a total of $1.6 million in license fees and $0.1 million in milestone payments under this agreement. We anticipate that we will pay up to an additional $0.4 million in milestone payments over the remaining term of the agreement. This agreement terminates upon the expiration of the last of the patent rights that are subject to this agreement, which is expected to occur in April 2017. This agreement may be terminated by PHRI upon a material breach of the agreement that is not cured following 30 days written notice, or by us for any reason following 30 days written notice.

Exclusive License with DiagnoCure. In November 2003, we entered into a license and collaboration agreement with DiagnoCure under which we agreed to develop in collaboration with DiagnoCure, and we agreed to market, a test to detect a new gene marker for prostate cancer. The diagnostic test is expected to detect a recently described gene called PCA3(DD3) that has been shown by studies to date 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 next three years. As of December 31, 2004, approximately $5.7 million remained to be paid to DiagnoCure pursuant to this obligation during the remainder of its three year term. We received exclusive worldwide distribution rights under the agreement to any products for the diagnosis of prostate cancer resulting from the agreement, and agreed to pay DiagnoCure royalties of 8% on cumulative net product sales of up to

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$50.0 million, and royalties of 16% on cumulative net sales above $50.0 million. This agreement expires, on a country-by-country basis, on the expiration of our obligation to pay royalties to DiagnoCure, which such 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 point-of-use NAT instrument 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 intend to evaluate 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 varies between $5.9 and $7.0 million, depending on the timing of the option exercise. In addition, we may pay Qualigen up to $3 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 technology for molecular diagnostic tests to detect prostate and other cancers. Under the terms of the agreement, we paid AdnaGen license fees of $1.0 million, and will pay $0.8 million on the later of February 1, 2006 or upon issuance to AdnaGen of a patent containing valid claims that cover products licensed under the agreement. 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 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 developed 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 such obligation remains in effect as long as the licensed products are covered by a valid claim of the licensed technology. Gen-Probe may terminate the agreement in its sole discretion upon 30 days prior written notice to AdnaGen, provided Gen-Probe has made any outstanding payments required under the agreement. Either party may terminate the agreement for cause by written notice to the other party of an uncured material breach by the other party or if the other party is unable to pay its debts or enters into compulsory or voluntary liquidation.

License Agreement with Corixa Corporation. In January 2005, we entered into a license agreement with Corixa Corporation pursuant to which we received the right to develop molecular diagnostic tests for 46 potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancer. Pursuant to the terms of the agreement, we paid Corixa an initial access license fee of $1.6 million and agreed to pay an additional $3.2 million in two equal access fees of $1.6 million on each of January 31, 2006 and January 31, 2007, unless we terminate the agreement prior to those dates. 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 using Corixa s technology. The agreement will expire on the expiration of our obligation to pay royalties to Corixa under the agreement, which such 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

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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. We currently own or have rights to 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 and foreign 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. 119 of our United States patents issued from applications filed prior to June 8, 1995. Our remaining 84 United States patents issued from applications filed on or after June 8, 1995. Two of our United States patents which issued from applications filed on or after June 8, 1995 are design patents which 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 September 28, 2021. 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, there can be no assurance that these patents will provide sufficiently broad protection to prevent competitors from selling products based on ribosomal nucleic acid detection in markets outside North America. In the United States, the last-to-expire of the Kohne patents remains in effect until March 3, 2015.

We also rely in part on trade secret protection for our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. The source code for our proprietary software is protected both as a trade secret and as copyrighted work. Our employees also sign agreements requiring that they assign to us their interests in inventions and original expressions and any corresponding patents and copyrights arising from their work for us. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, there may not be an adequate corrective remedy available.

Competition

The medical diagnostics and biotechnology industries are subject to intense competition. Our competitors in the United States and abroad are numerous and include, among others, diagnostic, health care, pharmaceutical and biotechnology companies. Our major competitors in the market for NAT diagnostics include F. Hoffmann-La Roche Ltd. and its subsidiary Roche Molecular Diagnostics, 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 market for NAT diagnostics are sensitivity, specificity, ease of use, potential for automation, cost, proprietary position, regulatory approvals and compliance and availability of appropriate reimbursement.

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Many of our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than we do. Moreover, many of our competitors offer broader product lines and have greater brand recognition than we do, and offer price discounts as a competitive tactic. In addition, there can be no assurance that competitors, many of which have made substantial investments in competing technologies, will not prevent, 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 F. Hoffmann-La Roche Ltd. and its subsidiary Roche Molecular Diagnostics, 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 Molecular Systems, 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 Molecular Systems and Becton Dickinson, 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 Molecular Diagnostics, 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 technologies and blood substitutes.

Chiron, with whom we have entered into an agreement for our blood screening products, retains certain rights to grant licenses of the patents related to HCV to third parties. Chiron has granted a license to Roche Molecular Diagnostics in the blood screening field and has granted licenses to other companies in the clinical diagnostic field. To the extent that Chiron grants additional licenses, further competition may be created for sales of HCV assays and such licenses may affect the prices that can be charged for our products.

Government Regulation

Our clinical diagnostic products generally are classified in the United States as devices and are regulated by the FDA s Center for Devices and Radiological Health. Our blood screening products generally are classified in the United States as biologics and are regulated by the FDA s Center for Biologics Evaluation and Research. The FDA also has the authority to revoke previously granted marketing authorizations.

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) or premarket approval application, or PMA, for the modified product before we are permitted to market it in the U.S. 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.

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,

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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.

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 submitted to the FDA. Our clinical department has comprehensive experience with clinical trials of NAT products.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include:

- the Quality System Regulation, which requires manufacturers to follow elaborate 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, 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 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.

Our clinical trial programs for blood screening products were developed in conjunction with our primary end users, The American Red Cross, America s Blood Centers and American Independent Blood Centers. Pivotal clinical trials of the Procleix HIV-1/HCV assay were completed in 2000, and our BLA 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.

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The results of product development and human studies are submitted to the FDA as part of the 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. Once approved, the FDA may withdraw the 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, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals.

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

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

We and all of our contract 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. Failure to comply with the statutory and regulatory requirements would subject the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Outside the United States, our ability to market our products is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, we apply for foreign marketing authorizations at a national level, although within the European Union registration procedures are now in effect under the IVD directive to companies wishing to market a product in more than one European union member state. We have taken the necessary actions to register our products for sale into the European Economic Community following a new requirement which became effective in December 2004.

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

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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 environment requirements. Because the requirements imposed by these laws and regulations frequently change, we are unable to predict the cost of compliance with these requirements in the future, or the effect of these laws on our capital expenditures, results of operations or competitive positions.

Manufacturing and Raw Materials

We have two state-of-the-art manufacturing facilities. Our 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 a manufacturing facility located in Rancho Bernardo, California for the manufacture of our blood screening products. This facility meets the strict standards set by the FDA s Center for Biologics Evaluation and Research for the production of blood screening products. 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. This facility has the capacity to produce sufficient tests to satisfy current global demand for these blood screening assays. 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 our only manufacturer of the 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 manufacturing 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 in manufacturing 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 the 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 The British Standards Institute, leading to our initial ISO 9001 certification. We have subsequently employed TUV North America for ISO 9001, EN 46001, EN 13485 and Diagnostic CE marking activities.

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Research and Development

As of January 31, 2005, we had 249 full-time and temporary employees in research and development. Our research and development expenses were $68.5 million in 2004, $63.6 million in 2003 and $47.0 million in 2002.

Employees

As of January 31, 2005, we had 809 full-time employees, of whom 175 hold advanced degrees, 225 were in research and development, 99 were in regulatory, clinical and quality systems, 135 were in sales and marketing, 124 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 January 31, 2005 we had 101 temporary employees.

Factors That May Affect Future Performance

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 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 2004 and will continue to incur expense in 2005 and beyond. 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 accurately. Our share of revenue under our blood screening collaboration with Chiron, from commercial sales of assays that test for HCV, decreased to 45.75% of net revenues as of January 1, 2004, as a result of the amendment to our collaboration agreement with Chiron. In addition, we base our internal projections of our international sales on projections prepared by our distributors of these products, 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.

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 35% of our total revenues for 2004 and 37% of our total revenues for 2003. Our agreements with Chiron and Bayer will terminate in 2010 unless extended. Both the Chiron and Bayer agreements can be extended by the development of new products under the agreements, in which case they 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 related primarily to the propriety of various deductions from gross revenues made by Chiron prior to calculating Gen-Probe s share of revenues and the parties respective shares of revenues received from The American Red Cross prior to FDA approval of the Procleix HIV-1/HCV blood screening assay. Other disputed items included the parties respective obligations in connection with clinical trials of the Procleix HIV-1/HCV blood screening assay and future assays, Chiron s obligation to purchase blood screening assays in compliance with its forecasts and the parties respective obligations with respect to

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royalties to be paid on a patent license from a third party. By December 2001, we negotiated a resolution to most of the disputed items, and in January 2002, we received $6.9 million in partial settlement of the claims. 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.

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. Accordingly, we are seeking confirmation that the agreement grants us, 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 has also been 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. The arbitrator agreed to review additional written testimony following closing arguments, and has informed the parties that he intends to issue a written decision on or about March 25, 2005. There can be no assurances as to the final outcome of the arbitration or when it may occur.

We rely upon bioMérieux for distribution of some of our products in most of Europe, Rebio Gen, Inc. for distribution of some 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 Gen-Probe upon termination. Our distribution agreement with Rebio Gen, terminates on December 31, 2005.

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 would 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 would 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. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct their 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. In addition, we expect to rely on our corporate collaborators for the commercialization of some of our products.

The continuation of any of our collaboration agreements may depend on periodic renewal by us and our collaborators of our corporate collaborations. Our agreements with Chiron and Bayer will terminate in 2010 unless extended by the development of new products under the agreements, in which case they 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. Both collaboration agreements are also subject to termination prior to expiration upon a material breach by either party to the agreement.

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If any of our collaboration agreements is terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to devote additional internal resources to product development or marketing or to terminate some development programs or seek alternative corporate collaborations. We may not be able to negotiate additional corporate collaborations on acceptable terms, if at all, and these collaborations may not be successful.

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 usually require operating and reliability improvements following their initial introduction. We believe that our experience with our TIGRIS instrument, now in its early introduction stage, 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 already 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. 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 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 F. Hoffmann-La Roche Ltd. and its subsidiary, Roche Molecular Diagnostics, Inc., Abbott Laboratories, Becton Dickinson and Company and bioMérieux S.A., 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. Some 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 a stronger 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. We believe that our competitors are developing real time or kinetic nucleic acid assays and are developing semi-automated instrument systems to perform real time 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 Molecular Systems, which received FDA approval of its Polymerase Chain Reaction, or PCR, based NAT tests for blood screening in December 2002. We also compete with assays developed internally by blood banks and laboratories based on PCR technology, an HCV antigen assay marketed by Ortho Clinical Diagnostics, a subsidiary of Johnson &

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Johnson, and immunoassay products from Abbott Laboratories. In the future, our blood screening products also may compete with viral inactivation 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 Molecular Systems in the blood screening and clinical diagnostics fields. Chiron has granted HIV and HCV licenses in the clinical diagnostic 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). 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 profit margin on the sale of blood screening assays may decrease upon the implementation of individual donor testing.

We currently receive revenues from the sale of the Procleix HIV-1/ HCV blood screening assay for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test, however, Chiron sells our Procleix HIV-1/ HCV assay 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 Procleix HIV-1/ HCV assay. 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 margins 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 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 47% of our total revenues for 2004 and 42% of our total revenues for 2003. 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 the year ended December 31, 2004. 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 for 2004 and 21% of our total revenues for 2003. Although state and city public health agencies are legally independent of each other, 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 have 202 United States patents and 188 foreign patents, these patents, or any patents that we may own or license in the future, may not afford meaningful protection

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for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by September 28, 2021, 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. Moreover, 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 may 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. Because we produce and provide many different products and services in this industry, we have faced in the past, are currently facing, and may face in the future, patent infringement suits by companies that control patents for products and services similar to ours or other suits alleging infringement of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management s attention from other business concerns. The cost of this litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

Recently, we have been involved in a number of patent disputes with third parties, a number of which remain unresolved. For example, we are in litigation with Enzo Biochem Inc. which claims that genetic sequences used in certain of our gonorrhea testing products infringe one of its patents.

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We may be subject to future product liability claims that may exceed the scope and amount of our insurance coverage, which would expose us to liability for uninsured claims.

While there is a federal preemption defense against product liability claims for medical products that receive premarket approval from the FDA, we believe that no such defense is available for our products that we market under a 510(k) clearance. As such, we are subject to potential product liability claims as a result of the design, development, manufacture and marketing of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates. In addition, we would have to pay any amount awarded by a court in excess of our policy limits. 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, 2004, we had approximately $150.6 million of long-lived assets, including $23.5 million of capitalized software relating to our TIGRIS instrument, goodwill of $18.6 million and $24.2 million of capitalized license fees, patents and purchased intangibles that have been included in Other assets on the face of the balance sheet. Additionally, we had $35.7 million of land and building, $5.5 million of leasehold improvements, $8.8 million of construction in-progress and $26.7 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. Such 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 to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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

The market for our products is 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, such as our NAT assay to detect WNV. For example, 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 will 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. Regulatory clearance or approval of any new products may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and the new products may not be successfully commercialized.

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We expect to continue to incur significant research and development expenses, which may make it difficult for us to maintain profitability.

In recent years, we have incurred significant costs in connection with the development of our blood screening 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 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 would 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, in the future we may need to incur additional debt or issue equity in order to fund these requirements as well as to make acquisitions and other investments. If we cannot obtain additional debt or equity financing on acceptable terms or are limited with respect to incurring additional 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 but not limited to the following:

for research and development to successfully develop our 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,

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 without limitation through the issuance of equity or debt securities pursuant to our Form S-3 shelf registration statement that we filed on August 29, 2003 with the Securities and Exchange Commission 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 the 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 dilute your ownership interest in us.

We expect to fund future acquisitions in part by issuing additional equity. If the price of our equity is unacceptably low or volatile due to market volatility or other factors, we may not be able to acquire other companies.

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 assurance, quality and costs.

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is our only manufacturer of our TIGRIS instrument. MGM Instruments, Inc. is the only manufacturer of our

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LEADER series of luminometers. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have no firm long-term commitments from KMC Systems, MGM Instruments or any of our other manufacturers to supply products to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order. If KMC Systems, MGM Instruments or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its manufacturing operations or becomes insolvent, then product shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation.

Further, our business would be harmed if we fail to manage effectively the 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 compliance with regulatory requirements, in sufficient quantities, on a timely basis and at acceptable costs, our ability to sell our products will be harmed.

We must manufacture our products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. 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.

In addition, the amplified NAT tests that we are producing 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. 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 margins. 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 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 products must be manufactured in compliance with guidelines set forth by the FDA s Center for Biologics Evaluation and Research, and our clinical diagnostic products must be manufactured in compliance with the guidelines set forth by the FDA s Center for Devices and Radiological Health. Maintaining compliance with more than one division of the FDA adds complexity and cost to our overall manufacturing processes. In addition, our manufacturing facilities and those of our contract manufac-

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turers are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies, and these facilities are subject to Quality System Regulations requirements of the FDA. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

Our products are subject to recalls even after receiving FDA approval or clearance.

The FDA and governmental bodies in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to product manufacturing, product 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 harm our reputation with customers.

In the past, we have had four voluntary recalls. The first product recall occurred in September 1999, when we responded to customer complaints about an increase in the number of our Mycobacterium Tuberculosis Direct, or MTD, assays demonstrating lower amplification of some test specimens. The formulation problem was identified and corrected. The second recall occurred in February 2000 when we recalled our MTD product due to decreased stability of a reagent in certain kit lots. The problem was identified and rectified through a voluntary field correction. The third recall occurred in July 2002 following the discovery of an error in the Chiron Procleix System software used with the Procleix HIV-1/ HCV blood screening assay and instruments. A review of prior test results determined that the defect did not cause any inaccurate results. The problem was rectified in a subsequent software update, which was submitted to and approved by the FDA. The fourth recall occurred in June 2004 as a result of a customer complaint about our MTD 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 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 15% of our total revenues for 2004 and 13% of our total revenues for 2003. Sales by Chiron outside of the United States accounted for 58% of our international revenues for both 2004 and 2003. Chiron has responsibility for the international distribution of our blood screening products, which includes sales in France, Australia, Singapore, New Zealand, Italy and other countries. Our sales in France and Japan that were not made through Chiron accounted for 10% and 6%, respectively, of our international sales for 2004 and 16% and 10%, respectively, for 2003.

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

In addition, we 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

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assay that screens 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.

We believe that the international market for our products is important, and therefore we seek patent protection for our products in foreign countries where we feel such protection is needed. Because of the differences in foreign patent and other laws concerning proprietary rights, our products may not receive the same degree of protection in foreign countries as they would in the United States.

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

We sell our 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 also 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 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 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 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 Systems, which is one of our primary competitors and the purchaser of Boehringer-Mannheim GmbH, with whom we had originally contracted for supplies. 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 have products under development which, if developed, may require us to enter into additional supplier arrangements. We also have single source suppliers for proposed future products. Failure to maintain existing supply relationships or obtain suppliers for our future products, if any, on commercially reasonable terms, would prevent us from manufacturing our future products and limit our growth.

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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. If our license with respect to any of these technologies is terminated for any reason, we will not be able to sell products that incorporate the technology. In addition, although our research staff seeks to discover particular nucleic acid sequences for targeted diseases, 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. Likewise, our ability to design products that target these diseases may be based 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 obtain access to 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.

Similarly, 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, and 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 not be able to hire or retain qualified personnel if we are unable to offer competitive salaries and benefits, or if our stock does not perform well.

We may acquire other businesses or form joint ventures that could decrease our profitability, dilute your ownership of us, increase our debt or cause us to incur significant expense.

As part of our business strategy, we intend to pursue acquisitions of other complementary businesses and 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 with respect to the formation of collaborations, strategic alliances and joint ventures. If we make future acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we could assume unknown or contingent liabilities. 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.

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To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. 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 and, in the case of equity financings, may result in dilution to our stockholders.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with these regulations and develop products compatible with 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 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, we were prohibited from commercially marketing our blood screening products in the United States until we obtained approval of our Biologics License Application from the FDA s Center for Biologic Evaluation and Research. 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 material 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.

Outside the United States, our ability to market our products is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, we apply for foreign marketing authorizations at a national level, although within the European Union, registration procedures are available to companies wishing to market a product in more than one European union member state. We are currently taking action to have our products registered for sale into the European Economic Community following a new requirement that became effective in December 2004. Failure to receive, or delays in the receipt of, relevant foreign qualifications could prevent us from selling our products in foreign countries.

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.

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

We manufacture all of our 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. The facilities may be harmed by natural or man-made disasters, including, without limitation, earthquakes and fires, and in the event they were 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 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 such 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 you may favor.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws also 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 you 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.

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We may not successfully integrate acquired businesses or technologies.

In August 2003, we acquired a majority of the outstanding shares of Molecular Light Technology Limited and its subsidiaries and in the future, we may acquire additional businesses or technologies, or enter into strategic transactions. Managing these acquisitions and any future acquisitions will entail numerous operational and financial risks, including:

the inability to retain key employees of any acquired businesses or hire enough qualified personnel to staff any new or expanded operations;

the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;

the exposure to federal, state, local and foreign tax liabilities in connection with any acquisition or the integration of any acquired businesses;

the exposure to unknown liabilities;

higher than expected acquisition and integration costs that would 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 would be difficult and costly; and

integrating or completing the development and application of any acquired technologies, which would 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 and address the foregoing concerns, 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 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. 123R, Share-Based Payment. This statement eliminates the ability to account for stock-based compensation using the intrinsic value method allowed under APB 25 and requires such 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 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 $11.0 million and $3.1 million for fiscal 2004 and 2003, respectively.

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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 plan to complete the implementation of a new general ledger information system and data warehouse to replace our current systems over the next two years. As a part of this effort, we are rationalizing various legacy systems and upgrading existing hardware and software applications and implementing new data management applications to administer our business information. We may not be successful in implementing the new system, and transitioning data and other aspects of the process could be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the implementation of this new system or any future systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flow and to otherwise operate our business, which could adversely affect our financial results, stock price and reputation.

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

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

Item 2. ***Properties***

Our worldwide headquarters are located in a 262,000 square-foot facility located in San Diego, California. We currently own this facility, the land on which it sits and an adjacent 22-acre parcel. We are currently building a 291,000 square-foot facility on our adjacent 22-acre parcel to support our company-wide growth. Approximately 100,000 square feet of the new facility will be left vacant for future expansion and primarily will be used for research and development, office space and warehousing of finished goods and distribution. We anticipate that construction of the facility will be complete in mid 2006 and will cost approximately $44 million, of which $6.3 million was capitalized to construction in-progress during 2004.

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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	Original term of 10 years with three five-year renewal options
Mira Mesa Facility San Diego, California	29,133 square feet	Original term of 3 years with one one-year renewal option
Wateridge Facility San Diego, California	29,141 square feet	Original term of 3 years with no renewal options
Rehco Facility San Diego, California	20,686 square feet	Original term of 3 years with no renewal options

Item 3. ***Legal Proceedings***

We are a party to the following litigation and are currently participating in other litigation in the ordinary course of business. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. 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, we were sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that we 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. Enzo has asserted a damage claim based on a contention that Enzo is entitled to a reasonable royalty on all sales of our products for the detection of *Neisseria gonorrhoeae* bacteria from June 1993 through trial. Revenues from tests for the detection of *Neisseria gonorrhoeae* have constituted a significant portion of our revenues during the relevant period. We believe that the claims of the 659 patent are invalid, unenforceable and may not be properly interpreted to cover our products. In July 2004, the Court granted summary judgment in favor of us and the other defendants and against Enzo, holding that the 659 patent is invalid based on the on-sale doctrine. Enzo has appealed the summary judgment to the United States Court of Appeals for the Federal Circuit. The parties have not yet completed their submissions of briefs to the Court of Appeals. The Company intends to vigorously defend the lawsuit. However, there can be no assurance that the case will be resolved in our favor.

Bayer Corporation

In November 2002, we 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 our collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. 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 viruses and other specified viruses, subject to certain conditions. Our demand for arbitration states that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. The arbitration demand seeks confirmation that the agreement grants us, 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 has also been 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. The

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arbitrator agreed to review additional written testimony following closing arguments, and has informed the parties that he intends to issue a written decision on or about March 25, 2005. There can be no assurances as to the final outcome of the arbitration.

On March 17, 2004, the Company filed a patent infringement action in the United States District Court for the Southern District of California against Bayer Corporation and Bayer Healthcare LLC, alleging 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. 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 patent is invalid or unenforceable. No trial date has been set. There can be no assurances as to the final outcome of the litigation.

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, 2004.

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. All share prices reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003.

	High	Low
2003		
First Quarter	$ 14.23	$ 10.38
Second Quarter	$ 21.93	$ 10.88
Third Quarter	$ 34.37	$ 20.05
Fourth Quarter	$ 38.00	$ 21.45

	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

As of March 1, 2005, there were approximately 7,639 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, 2004 and, with respect to our consolidated balance sheets, at December 31, 2004 and 2003 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 (loss) data for the years ended December 31, 2001 and 2000 and the balance sheet data as of December 31, 2002, 2001, and 2000 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.

	2004	2003	2002	2001	2000
			(In thousands, except per share data)		
Statement of income (loss) data for the years ended December 31:					
Revenues:					
Product sales	$ 222,560	$ 188,645	$ 139,932	$ 104,233	$ 100,162
Collaborative research revenue	27,122	15,402	11,032	20,203	13,764
Royalty and license revenue	20,025	3,144	4,633	5,295	5,615
Total revenues	269,707	207,191	155,597	129,731	119,541
Operating expenses:					
Cost of product sales	59,908	45,458	53,411	38,954	34,463
Research and development	68,482	63,565	47,045	54,915	59,902
Marketing and sales	27,191	22,586	18,199	16,247	14,508
General and administrative	31,628	23,233	20,995	15,564	12,628
Total operating expenses	187,209	154,842	139,650	125,680	121,501
Income (loss) from operations	82,498	52,349	15,947	4,051	(1,960)
Net income (loss)	$ 54,575	$ 35,330	$ 13,007	$ 4,617	$ (1,008)
Net income (loss) per share					
Basic	$ 1.10	$ 0.74	$ 0.27	$ 0.10	$ (0.02)
Diluted	$ 1.06	$ 0.72	$ 0.27	$ 0.10	$ (0.02)
Weighted average shares outstanding					
Basic	49,429	47,974	47,600	47,600	47,600
Diluted	51,403	49,137	47,610	47,606	47,600
Balance sheet data as of December 31:					
Cash, cash equivalents and short-term investments	$ 193,826	$ 156,306	$ 107,960	$ 17,750	$ 12,584
Working capital	234,202	169,000	115,288	29,765	29,439
Total assets	411,082	324,741	258,157	160,347	156,612
				12,000	14,000

Long-term debt, including current portion					
Stockholders equity	361,029	270,375	215,578	115,807	111,180

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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 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 included herein under the caption Risk Factors in Item 1. Business. 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, 2004, 2003 and 2002 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 the screening of donated human blood. We have over 22 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 major countries throughout the world.

In September 2002, our common stock began trading on the NASDAQ National Market. As a publicly traded company, 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, 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.

Recent Events

Financial Results

During 2004, we achieved strong financial results. Net income for the year was $54.6 million ($1.06 per diluted share), compared to $35.3 million ($0.72 per diluted share) in 2003, an increase of 54%. Total revenues for 2004 were $269.7 million, compared to $207.2 million in 2003, an increase of 30%. Product sales for 2004 were $222.6 million, compared to $188.6 million in 2003, an increase of 18%. During 2004, net income and total revenues 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 $0.17 to diluted earnings per share and $13.5 million to revenues.

Corporate Collaborations

In January 2005, bioMérieux and its affiliates exercised an option to develop diagnostic products for certain undisclosed disease targets using our patented ribosomal RNA technologies, pursuant to the terms of a September 2004 agreement. In exchange for these rights, bioMérieux and its affiliates paid us a $4.5 million license fee. We have recorded $1.9 million of the cumulative payments ($4.5 million license fee and $0.25 million option fee) as license revenue in the first quarter of 2005, based on the total number of targets that may eventually be selected. The amount and timing of additional revenue that we record will depend on the number of additional targets, if any, selected by bioMérieux, which also has options to develop diagnostic products for other disease targets by paying us up to an additional $3 million by the end of 2006. Further, we will receive royalties on the sale of any products developed by bioMérieux using our intellectual property.

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In January 2005, we also entered into a license agreement with Corixa Corporation, or Corixa, and received the right to develop molecular diagnostic tests for approximately 50 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 license fee of $1.6 million and agreed to pay an additional $3.2 million in two equal access fees of $1.6 million on January 31, 2006 and January 31, 2007, unless we terminate the agreement prior to those dates. We expect to record the initial $1.6 million license fee as an intangible asset which will be amortized over the underlying life of the patents or the term of our rights to these patents, whichever expires sooner. 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. Further, 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 gain access to technology that may help increase the accuracy of molecular diagnostic tests to detect prostate and other cancers. Under the terms of the agreement, we paid AdnaGen a license fee of $1.0 million, and agreed to pay $750,000 on the later of February 1, 2006 or upon issuance to AdnaGen of a patent containing valid claims that cover products licensed under the agreement. We recorded the $1.0 million license fee as R&D expense in 2004 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 exclusive option agreement with Qualigen, Inc. to develop and commercialize a point-of-use NAT instrument 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 and genetic mutations. Under the terms of the agreement, we paid Qualigen $1.0 million for an 18-month option to license, on an exclusive basis, Qualigen s technology to develop NAT assays for the clinical diagnostics, blood screening and industrial fields. During this period, we intend to evaluate the feasibility of adapting Qualigen s immunoassay platform to perform NAT using our proprietary technologies. If we exercise this option, at our sole discretion, then we have agreed to purchase shares of Qualigen preferred stock convertible into approximately 19.5% of Qualigen s then outstanding fully diluted common shares outstanding. The cost of acquiring this equity interest would vary between $5.9 and $7.0 million, depending on the timing of the option exercise. In addition, we may pay Qualigen up to $3.0 million in license fees based on development milestones, and agreed to pay royalties on any 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 the Company withdrew its patent litigation against Vysis and agreed to pay Vysis an aggregate of $22.5 million. This amount included $20.5 million for a fully paid up license to eliminate all future royalty obligations of the Company 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. The Company 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 under their collaboration agreement with us to reimburse the Company a portion of the royalties paid by the Company to Vysis on 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.

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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 will manufacture and supply DNA probes for human papillomavirus, or HPV. We will use these probes in molecular diagnostic assays. Pursuant to the agreement, we will pay Roche manufacturing fees of $20.0 million within 90 days of February 15, 2005 and $10.0 million within 10 days of the occurrence of certain future commercial events. We also agreed to pay Roche transfer fees for the HPV products.

Product Development

We submitted a Biologics License Application, or BLA, for the West Nile virus, or WNV, assay to the U.S. Federal Drug Administration, or FDA, during the first quarter of 2005. Approximately 1200 infected units have been intercepted using our WNV assay since July of 2003. In addition, our high-throughput TIGRIS instrument was used by several blood centers to screen both individual donor and pooled blood donations for WNV.

We submitted a BLA for the Procleix Ultrio (HIV-1/ HCV/ HBV) assay to the FDA during the third quarter of 2004. We intend to seek approval to run the test on both the semi-automated Procleix system and on the fully automated TIGRIS instrument. We also submitted a regulatory application to European officials to run the Procleix Ultrio assay on our TIGRIS instrument. In January 2004, the Procleix Ultrio assay, running on our semi-automated instrument system, received its Community European, or CE, mark, which permitted Chiron to launch the product in the European Economic Area. Our TIGRIS instrument and our Procleix Ultrio assay for use on the TIGRIS instrument, received CE marks in December 2004.

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 we 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, including the National Institutes of Health, or NIH, 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 2004, product sales, collaborative research revenues and royalty and license revenues equaled 83%, 10% and 7%, respectively, of our total revenues of $269.7 million.

Product sales

Our primary source of revenue is the sale of clinical diagnostic products in the United States, which include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During 2004, we shipped approximately 22 million tests for the diagnosis of a wide variety of infectious microorganisms, including those causing sexually transmitted diseases, or 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 a contractual transfer price, through our collaboration with Chiron, to blood bank facilities located in the 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

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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 continue to receive reimbursement for our manufacturing costs plus 50% of net revenues. 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 price restrictions applied to these products prior to FDA license approval in the United States and similar approvals in foreign countries. In 2004 and 2003, we recognized $18.5 million and $6.0 million, respectively, as collaborative research revenue through our collaboration with Chiron from deliveries of WNV tests on a cost recovery basis. Our NAT assay to detect WNV is currently being used in clinical trials under an Investigational New Drug, or IND, application. In 2004, we recognized $1.4 million in reimbursements for expenses incurred for WNV. We expect to continue recognizing these sales as collaborative research revenue until FDA approval has been received, although there is no guarantee we ultimately will receive FDA approval.

In March 2003, we signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. In 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.

We recognize collaborative research revenue over the term of our strategic alliance agreement with Chiron 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 the collaborative research revenue.

Since 1996, we have been awarded contracts aggregating approximately $28.2 million by the NIH to develop NAT assays for screening donated blood for HIV-1, HCV, hepatitis B virus, or HBV, and WNV. To date, all payments due to us under these reimbursement contracts have been received and have been recorded as collaborative research revenues as reimbursable costs were incurred. As of December 31, 2004, the Company has billed all monies remaining under these contracts.

Royalty and license revenue

We recognize non-refundable up-front license fees over the performance period of the applicable agreement or at the time that we have satisfied all substantive performance obligations under such 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, and (iii) the fees are non-refundable.

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Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue on our balance sheet.

In December 2003, we entered into an agreement with Tosoh 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 agreement, Tosoh received non-exclusive rights to our proprietary Transcription-Mediated Amplification, or TMA, and rRNA technologies in exchange for two payments to us totaling $7.0 million. These payments were recognized as revenue in the first quarter of 2004 as there were no additional obligations placed on us after the effective date of the contract and the transfer of rights to the technology. Further, Tosoh agreed to pay us royalties on worldwide sales of any future products that employ our technologies licensed by Tosoh. We also have gained access, in exchange for the payment of royalties, to Tosoh s patented Transcription Reverse-Transcription Concerted, or TRC, amplification and Intercalation Activating Fluorescence, or INAF, detection technologies for use with our real time TMA technology.

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 the first quarter of 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. An additional payment of $10.0 million is due to us in the future under the agreement if we obtain FDA approval of our Ultrio assay for use on the TIGRIS instrument. There is no guarantee we will achieve these milestones and receive any additional milestone payments under this agreement.

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. Indirect cost elements, which include manufacturing variances, purchase price variances, and allowances for scrap are also included as a component of cost of product sales, as well as certain related expenses, such as royalties, warranty, and instrument amortization.

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 2004 and 2003, 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 to support In-Vitro Diagnostic, or IVD, sales abroad is charged to inventory and classified as cost of product sales upon shipment.

Our blood screening manufacturing facility has operated below its capacity 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 IND application, are classified as research and development expense prior to FDA approval.

Effective January 1, 2004, our revenue sharing percentage with Chiron was reduced from 47.5% to 45.75%. This change, combined with higher instrument costs, including the amortization of our capitalized software development costs (which we began to amortize in 2004) and related service costs attributed to the general commercial launch of our TIGRIS instrument, contributed to lower 2004 gross margin percentage levels. In addition, our non-military customers currently utilize pooled blood screening samples for testing. We anticipate that requirements for smaller pool sizes or ultimately individual donor testing, 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 is implemented. We are not able to accurately predict the extent to which our gross margin may be 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 is implemented.

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Research and development

We invest significantly in research and development, or 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 which 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. During 2005, we expect to incur further incremental 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 incurred costs have at times been realized in a period later than when incurred due to the need for further clarity 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 accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectibility of accounts receivable, valuation of inventories, long-lived assets including patent costs and capitalized software, 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 by Chiron.

We manufacture our blood screening products according to Chiron s demand specifications and transfer/shipment of completed product to Chiron s virtual warehouse, which consists of various interim locations on our premises. Upon transfer/shipment of completed product to Chiron s virtual warehouse, we bill Chiron at a cost recovery transfer price, and Chiron remits payment in 30 days. We record amounts billed as deferred revenue until product shipment is made to Chiron s end-customers. Customer orders for the assay are received by Chiron and then communicated to our personnel who fulfill the orders and ship to Chiron s

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end-customers. Upon shipment to the end-customer, we recognize blood screening product sales at the transfer price and record cost of products sold at the cost of our assays. Blood screening product sales are adjusted upon our receipt of payment from Chiron of amounts reflecting our ultimate share of net sales by Chiron of these products, less the transfer price revenues previously paid.

Product sales also include the sales or rental value associated with the delivery of our proprietary integrated instrument platforms that perform our NAT assays. Generally, we provide our instrumentation to clinical laboratories and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, we recover the cost of providing the instrumentation in the amounts we charge for our diagnostic assays. The costs associated with an instrument are charged to costs 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 systems, and five years for TIGRIS and DTS 800/1600 systems. The costs to maintain these systems in the field are charged to operations as incurred.

We sell our instrumentation 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. Occasionally, we sell instrumentation 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 extensively 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 similar approvals in foreign countries. As commercial pricing is implemented, 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 that agreement. 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, and (iii) the fees are non-refundable. 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.

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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 the estimated market value 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 the 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 or 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 manufacture products that are sold into approved markets and also maintained for further development evaluations for other markets, we may also provide valuation allowances for this inventory due to the historical uncertainties associated with regulated product introductions. To the extent any of these previously manufactured products are sold to end users, we record revenues, subject to any applicable adjustments in royalty rates under our collaboration agreements with Chiron and others, and reduce any 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.

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.

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, 2004, capitalized software development costs related to our TIGRIS instrument totaled $23.5 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 certain STDs on our 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 the third quarter of 2004. If we are not able to successfully deliver this instrument to the

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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 during May 2004, coinciding with the general release of TIGRIS instruments to our customers.

Income taxes

Through December 31, 2002, we were included in the consolidated federal and in various combined state income tax returns of our former parent company, Gen-Probe Holding Company, Inc., formerly known as Chugai Pharma U.S.A., Inc.. Pursuant to a tax sharing agreement with Gen-Probe Holding Company, we generally were allocated an amount of the consolidated tax liability equal to the tax that would have been applicable if computed separately. At December 31, 2004, we had net deferred tax liabilities of $1.5 million, which relate to capitalized costs expensed for tax purposes and other items. These amounts are offset by research and investment credits filed in our tax returns, and timing differences arising from the recording of deferred revenue and certain reserves and accruals.

In connection with our merger with Gen-Probe Holding Company in 2002, we recorded approximately $2.8 million of deferred tax assets. These deferred tax assets related principally to financial statement depreciation in excess of that deducted for tax purposes and to research and development tax credits previously held by Chugai Pharma USA, LLC, the successor to our former sister company Chugai Biopharmaceuticals, Inc., which have been included in our combined tax returns. These deferred tax assets may be realized in future periods depending on, among other factors, whether we have sufficient future taxable income. The deferred tax assets are fully offset by a valuation reserve until these deductions and credits are realized. In the event that we were to determine that we would not be able to realize all or part of our deferred tax assets in the future, an adjustment to reduce the deferred tax asset would be made in the period such determination was made.

It is our policy to establish reserves based upon management s assessment of exposure for tax credits claimed in previously filed tax returns that may become payable upon audits by tax authorities. The tax reserves are analyzed at least annually and adjustments are made as events occur to warrant adjustments to the reserve.

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Results of Operations

The following table sets forth operating data as a percentage of total revenues:

	Years Ended December 31		
	2004	2003	2002
Total revenues	100%	100%	100%
Product sales	83%	91%	90%
Collaborative research revenue	10%	7%	7%
Royalty and license revenue			
Operating expenses:	7%	2%	3%
Cost of product sales	22%	22%	34%
Research and development	25%	31%	31%
Marketing and sales	10%	11%	12%
General and administrative	12%	11%	13%
Total operating expenses	69%	75%	90%
Income from operations	31%	25%	10%
Total other income (expense)	0%	2%	2%
Income before income taxes	31%	27%	12%
Income tax expense	11%	10%	4%
Net income	20%	17%	8%

Year Ended December 31, 2004 Compared to Year Ended December 31, 2003

(Percentages have been rounded to the nearest whole percentage)

Product sales

Product sales increased $34.0 million, or 18%, to $222.6 million in 2004 from $188.6 million in 2003. The increase was principally the result of a $19.0 million increase in worldwide commercial sales of our Procleix blood screening products, both in the United States and international markets, and a $13.1 million increase in STD product sales, primarily APTIMA. Procleix blood screening product sales represented $95.6 million, or 43% of product sales in 2004, compared to $76.6 million, or 41% of product sales, in 2003.

We expect competitive pressures related to our STD and blood screening products to continue into the foreseeable future, primarily as a result of the introduction of competing products into the market and continuing pricing pressure.

Collaborative research revenue

Collaborative research revenue increased $11.7 million, or 76%, to $27.1 million in 2004, from $15.4 million in 2003. The increase was primarily the result of a $12.6 million increase in firm support commitment payments in connection with the WNV 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 development costs. This increase was partially offset by a $1.9 million decrease in revenue from the NIH as our WNV 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

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relationships may not be established or maintained and current collaborative research revenue may decline. Shortly after FDA approval of our Procleix and Ultrio assays, we would expect Chiron to implement commercial pricing related to the use of these products 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 increased $16.9 million, or 545%, to $20.0 million in 2004, from $3.1 million in 2003. The 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 fully automated 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 revenues may depend, in part, on our ability to market and capitalize on our technologies. We may not be able to do so and future royalty and license revenue may decline.

Cost of product sales

Cost of product sales increased $14.4 million to $59.9 million, or 27% of product sales revenues in 2004, from $45.5 million, or 24% of product sales revenues in 2003. The $14.5 million increase in cost of sales was principally attributed to the volume increase in product sales, higher allowances for scrap expense and the amortization of capitalized software development costs related to our TIGRIS instrument. 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.

Our gross profit margin on product sales decreased to 73% in 2004, from 76% in 2003. The decrease was primarily the result of higher scrap expense of $5.8 million, including expiration of enzymes that were produced in support of the Procleix BLA; increased sales of lower margin products (including TIGRIS instruments), unfavorably impacting margin by approximately $1.8 million; and the amortization of capitalized software development costs of $1.7 million, which began in the second quarter of 2004; partially offset by lower unit costs on sales volume increases.

We anticipate that requirements for smaller pool sizes or ultimately individual donor testing, 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. We are not able to accurately predict the extent to which our gross margin 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 is implemented.

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 $4.9 million, or 8%, to $68.5 million, or 25% of total revenues, in 2004, from $63.6 million, or 31% of total revenues, in 2003. Increased R&D spending was comprised of a $9.0 million increase in expenses resulting from higher staffing levels to support product development projects and clinical trial efforts, a $2.2 million increase in expenses related to clinical trials for blood screening products, a $1.6 million increase in outside development research due to our aggregate license fees paid to DiagnoCure and AdnaGen and a $1.2 million increase in R&D expenses from our subsidiary, Molecular Light Technology

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Limited (acquired in August 2003). These increases were mostly offset by a $9.3 million decrease in development lot production and lower per unit costs.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $4.6 million, or 20%, to $27.2 million, or 10% of total revenues, in 2004, from $22.6 million, or 11% of total revenues, in 2003. The increased spending principally included a $3.7 million increase in salaries, benefits, commissions and other personnel related costs in our marketing, sales, and technical service organization to support APTIMA market expansion and TIGRIS instrument commercialization, together with 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, 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 $8.4 million, or 36%, to $31.6 million, or 12% of total revenues, in 2004 from $23.2 million, or 11% of total revenues, in 2003. The increased spending included 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, Molecular Light Technology Limited; 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 (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $2.1 million in 2004 represented a $0.6 million decrease from the net other income of $2.7 million in 2003, which was primarily due to a $0.5 million increase in realized foreign exchange rate losses.

Income tax expense

Income tax expense increased to $30.0 million, or 35.5% of pretax income, during 2004, from $19.8 million, or 35.9% of pretax income, in 2003. 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%.

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

(Percentages have been rounded to the nearest whole percentage)

Product sales

Product sales increased $48.7 million, or 35%, to $188.6 million in 2003 from $139.9 million in 2002. The increase was primarily the result of a $38.6 million increase in commercial sales of Procleix blood screening products, both in the United States and international markets, and a $10.3 million increase in STD product sales. Procleix blood screening product sales represented $76.6 million, or 41% of product sales, for the year ended December 31, 2003, compared to $38.0 million, or 27% of product sales, for the year ended December 31, 2002.

Collaborative research revenue

Collaborative research revenue increased $4.4 million, or 40%, to $15.4 million in 2003, from $11.0 million in 2002. The increase was primarily the result of a $4.2 million increase in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay. Additionally, revenues increased by $1.8 million in 2003 due to additional funds received from the NIH in November 2003 to develop a NAT

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assay for the detection of WNV. These increases were partially offset by a $1.1 million decrease in firm support commitment payments in connection with Procleix tests provided to United States customers through our collaboration with Chiron.

Royalty and license revenue

Royalty and license revenue decreased $1.5 million, or 32%, to $3.1 million in 2003, from $4.6 million in 2002. The decrease was primarily the result of $2.6 million in prepaid license fees and royalties from bioMérieux which were fully amortized as of December 31, 2002, partially offset by a $0.8 million increase in net license income from Bayer for the licensing of rights to certain patented technology and a $0.3 million increase in minimum annual royalties from bioMérieux.

Cost of product sales

Cost of product sales decreased $7.9 million to $45.5 million, or 24% of product sales revenues in 2003, from $53.4 million, or 38% of product sales revenues in 2002. The $7.9 million decrease in cost of sales principally consisted of a $15.6 million reduction in manufacturing costs related to costs absorbed by research and development for the production of pre-commercial development lots partially offset by a $7.0 million increase in cost of sales attributable to increases in sales volume.

Our gross profit margin on product sales increased to 76% in 2003, from 62% in 2002. The gross profit margin benefited by approximately $32.0 million, or 17%, of product sales, primarily from the implementation of commercial pricing in the United States for Procleix blood screening products, as well as an increase in our revenue sharing percentage with Chiron in the second quarter of 2003. Additionally, our margin benefited from certain manufacturing costs absorbed by research and development for the production of pre-commercial development lots.

Research and development

Our R&D expenses include salaries and other personnel-related expenses, temporary personnel expenses, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. R&D expenses increased $16.5 million to $63.2 million, or 31% of total revenues, in 2003, from $46.7 million, or 30% of total revenues, in 2002. The increase was primarily the result of a $12.9 million increase in the production of pre-commercial development lots built and expensed during the year, including three WNV and four Procleix Ultrio development lots, and a $2.3 million increase in salaries and temporary labor resulting from higher staffing levels.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $4.4 million, or 24%, to $22.6 million, or 11% of total revenues in 2003, from $18.2 million, or 12% of total revenues in 2002. The increase in expenses was primarily related to a $1.5 million increase in professional consulting and personnel costs in our marketing and sales force to support increases in sales for our clinical diagnostic products.

General and administrative

Our G&A expenses include personnel costs for finance, legal, public relations, human resources and business development, as well as professional fees, such as expenses for legal, patents and auditing services. G&A expenses increased $2.2 million, or 10%, to $23.2 million, or 11% of total revenues, in 2003, from $21.0 million, or 13% of total revenues, in 2002. The increase was principally the result of a $2.2 million increase in salaries and benefits resulting from higher staffing levels, including our August 2003 acquisition of the majority ownership of Molecular Light Technology Limited, partially offset by a $1.1 million decrease in professional fees primarily attributed to our 2002 spin-off from Chugai Pharmaceutical Co., Ltd.

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Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $2.7 million in 2003 represented a $0.4 million increase over 2002. During 2003, we reclassified a $1.25 million charge associated with the early repayment of debt, which was previously recorded as an extraordinary loss. In addition, there was a $1.5 million increase in 2003 in interest income from our short-term investments, a portion of which was from interest earned on Molecular Light Technology Limited investment balances. Partially offsetting these net increases to other income, in 2002 we received in cash and recognized other income from settlements of outstanding contractual issues with Chiron in the amount of $2.4 million and from a former vendor in the amount of $1.2 million.

Income tax expense

Income tax expense increased to $19.8 million, or 35.9% of pre-tax income, during 2003 from $5.2 million, or 28.6% of pre-tax income, in 2002. The increase in our effective tax rate in 2003 was principally attributed to higher profits taxed at the combined federal and state statutory tax rate of approximately 41%, partially offset by the benefit of federal and state research and investment credits.

Liquidity and capital resources

	2004	2003	2002
December 31:			
Cash, cash equivalents and short-term investments	$ 193,826	$ 156,306	$ 107,960
Working capital	234,202	169,000	115,288
Current ratio	8:1	5:1	5:1
Year Ended December 31:			
Cash provided by (used in):			
Operating activities	$ 62,284	$ 52,616	$ 42,237
Investing activities	(93,712)	(74,787)	(80,747)
Financing activities	20,438	14,888	63,878
Purchases of property, plant and equipment (included in investing activities above)	(26,021)	(12,238)	(12,616)

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, 2004, we had $193.8 million of cash and cash equivalents and short-term investments.

The $9.7 million increase in net cash provided by operating activities during 2004 was primarily the result of a $19.2 million increase in net income and a $14.0 million increase in stock option income tax benefits, partially offset by a $13.6 million increase in inventory and a $5.0 million decrease in income tax payable. The inventory increase was due, in large part, to the commercialization of our TIGRIS instrument and the European launch of the Proceix Ultrio assay.

The $18.9 million increase in our investing activities during 2004 included a net $17.0 million payment to Vysis for a fully paid up license to eliminate future royalty obligations under the patent covered by the license. In addition, our investing activities included a $13.8 million increase in capital expenditures, partially offset by a $5.2 million decrease in net purchases of short-term investments. Our 2004 growth in capital expenditures was primarily due to the construction of our new building and costs of our Enterprise Resource Planning, or 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. The average age of our property, plant and equipment is approximately five years, which provides us flexibility in planning capital expenditures.

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The $5.6 million increase in net cash provided by financing activities during 2004 was principally attributed to a $3.2 million increase in employee purchases of our common stock made through our Employee Stock Purchase Plan, or ESPP, and a $2.4 million increase 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.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2005, 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. Financial covenants include requirements as to tangible net worth, liabilities as a percentage of tangible net worth, the ratio of current assets to current liabilities, required minimum levels of earnings before interest, taxes, depreciation and amortization, the ratio of funded debt to earnings before interest, taxes, depreciation and amortization, and maximum levels of pre-tax and after tax losses. At December 31, 2004, we were in compliance with all covenants.

In July 2004, we commenced construction of an additional building to expand our main Genetic Center Drive 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 $44.0 million, of which $6.3 million was capitalized to construction in-progress during 2004. These costs are being capitalized as incurred and depreciation will commence upon our completion and use, which is planned for early 2006. These amounts are not included in the chart below.

We have recently implemented a new ERP software system which cost approximately $4.9 million in 2004. We expect to incur approximately $3.1 million of costs in 2005 for further improvement to the Company s ERP system.

Further, we expect to incur approximately $5.0 million to purchase TIGRIS instruments that will be added to our installed base during 2005.

Contractual obligations and commercial commitments

Our contractual obligations due to lessors for properties that we lease, as well as other amounts due for purchase commitments as of December 31, 2004 were as follows (amounts in thousands):

Contractual Obligations	Total	2005	2006	2007	2008	2009	Thereafter
Operating leases[1]	$ 5,045	$ 2,422	$ 1,762	$ 765	$ 96	$	$
Material purchase commitments[2]	15,085	15,085					
Total[3]	$ 20,130	$ 17,507	$ 1,762	$ 765	$ 96	$	$

(1) Reflects obligations on facilities under operating leases in place as of December 31, 2004. Future minimum lease payments are included in the table above.

(2) Amounts represent our minimum purchase commitments from two key vendors for raw materials used in manufacturing and instrumentation.

(3) 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.

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We have entered into various license and collaboration agreements which may require us to make future payments for fees, contract development payments, milestones, royalties, or equity investments. These amounts are not included in the chart above.

Our collaboration commitments include:

DiagnoCure. As part of our collaboration to develop a molecular diagnostic test that detects a new gene marker for prostate cancer, approximately $5.7 million remains to be paid to DiagnoCure pursuant to this obligation.

Corixa. As part of our license to develop molecular diagnostic tests for approximately 50 potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancer, approximately $5.2 million remains to be paid to Corixa.

Qualigen. If we exercise our option to develop a point-of-use NAT instrument, we will purchase an equity interest in Qualigen ranging from $5.9 to $7.0 million. Further, we may pay Qualigen up to $3.0 million based on development milestones.

AdnaGen. As part of our license to technology that may help increase the accuracy of molecular diagnostic tests to develop prostate and other cancers, we may pay AdnaGen up to $3.0 million based on achievement of certain milestones.

Our supply commitments include:

Roche. As part of our HPV DNA probes supply and purchase agreement, we will pay Roche $20.0 million in May 2005 and may pay $10.0 million upon achievement of certain commercial events. Further, we have agreed to pay Roche transfer fees for the HPV products.

Our primary short-term needs for capital, which are subject to change, are for expansion of our Genetic Center Drive 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 are funded under collaboration agreements with partners or agencies of the United States government.

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. Furthermore, additional debt financing may contain more restrictive covenants than our existing debt.

We may from time to time consider the acquisition of businesses and/or technologies complementary to our business. We could require debt financing if we were to engage in a material acquisition in the future. 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.

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 program primarily consists of three broad-based plans under which stock options are granted to employees, directors and other service providers. Substantially all of our employees have historically participated in our stock option program.

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors. Additional information regarding our stock option plans for 2004, 2003 and 2002 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

All of our equity compensation plans under which options are currently outstanding or under which shares remain available for future issuance as summarized below have been approved by our stockholders.

Summary of Option Activity

(Shares in thousands)

		Options Outstanding	
	Shares Remaining Available for Future Issuance	Number of Shares to be Issued upon Exercise	Weighted Average Exercise Price
December 31, 2002	502	4,678	$ 12.93
Grants	(2,044)	2,044	27.19
Exercises		(1,083)	13.20
Cancellations	166	(166)	16.34
Additional shares reserved	5,000		
December 31, 2003	3,624	5,473	$ 18.10
Grants	(2,061)	2,061	37.21
Exercises		(1,178)	14.15
Cancellations	352	(352)	24.97
Additional shares reserved			
December 31, 2004	1,915	6,004	$ 25.03

In-the-Money and Out-of-the-Money Option Information

(Shares in thousands)

	Exercisable		Unexercisable		Total	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
As of December 31, 2004						
In-the-Money	2,208	$ 16.73	3,758	$ 29.68	5,966	$ 24.89
Out-of-the Money(1)			38	47.32	38	47.32
Total Options Outstanding	2,208		3,796		6,004	

(1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of Gen-Probe Common Stock, $45.21, at the close of business on December 31, 2004.

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

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hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our financial instruments that are exposed to changes in interest rates.

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 majority 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 from transactions denominated in certain foreign countries, but the total receivables and payables denominated in foreign currencies at December 31, 2004 were not material. We believe that our business operations are not exposed to market risk relating to commodity price risk.

Item 8. ***Consolidated 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, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the year ended December 31, 2004.

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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, 2004 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, 2004.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein.

Item 9B. ***Other Information not previously reported on Form 8-K***

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 2005, 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.

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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, including both stockholder approved plans and non-stockholder approved 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 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.

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

Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

Consolidated balance sheets at December 31, 2004 and 2003

Consolidated statements of income for each of the three years in the period ended December 31, 2004

Consolidated statements of cash flows for each of the three years in the period ended December 31, 2004

Consolidated statements of stockholders equity for each of the three years in the period ended December 31, 2004

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, 2004

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. See part (c) below.

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

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SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

By: /s/ Henry L. Nordhoff

Henry L. Nordhoff
Chairman, President and Chief Executive Officer

Date: March 15, 2005

Pursuant to the requirements of the Securities and 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 15, 2005
/s/ Herm Rosenman Herm Rosenman	Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2005
/s/ Raymond V. Dittamore Raymond V. Dittamore	Director	March 15, 2005
/s/ Mae C. Jemison, M.D Mae C. Jemison, M.D	Director	March 15, 2005
/s/ Armin M. Kessler Armin M. Kessler	Director	March 15, 2005
/s/ Gerald D. Laubach, Ph.D. Gerald D. Laubach, Ph.D.	Director	March 15, 2005
/s/ Brian A. McNamee, M.B.B.S Brian A. McNamee, M.B.B.S	Director	March 15, 2005
/s/ Phillip M. Schneider Phillip M. Schneider	Director	March 15, 2005
/s/ Abraham D. Sofaer	Director	March 15, 2005

Abraham D. Sofaer

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GEN-PROBE INCORPORATED
CONSOLIDATED FINANCIAL STATEMENTS
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Gen-Probe Incorporated

We have audited the accompanying consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2004. Our audits also include 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, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, 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, 2004, 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 10, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 10, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of sponsoring organization 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, 2004, 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, 2004, 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, 2004 and 2003, and the related consolidated statements of income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2004 of Gen-Probe Incorporated and our report dated February 10, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 10, 2005

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

	December 31	
	2004	2003
Current assets:		
Cash and cash equivalents	$ 25,498	$ 35,973
Short-term investments	168,328	120,333
Trade accounts receivable, net of allowance for doubtful accounts of $664 and $717 at December 31, 2004 and 2003, respectively	21,990	15,158
Accounts receivable other	3,136	2,555
Inventories	27,308	13,676
Deferred income taxes	7,725	10,979
Prepaid expenses and other current assets	13,964	10,203
Total current assets	267,949	208,877
Property, plant and equipment, net	76,651	65,478
Capitalized software	23,466	24,872
Goodwill	18,621	18,621
Other assets	24,395	6,893
Total assets	$ 411,082	$ 324,741
Current liabilities:		
Accounts payable	6,729	9,250
Accrued salaries and employee benefits	11,912	11,670
Other accrued expenses	4,451	6,085
Income tax payable	1,188	6,191
Deferred revenue	9,467	6,681
Total current liabilities	33,747	39,877
Deferred income taxes	9,187	6,850
Deferred revenue	5,000	5,667
Deferred rent	309	323
Minority interest	1,810	1,649
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, 50,035,490 and 48,721,560 shares issued and outstanding at December 31, 2004 and 2003, respectively	5	5
Additional paid-in capital	248,767	212,586
Deferred compensation	(1,104)	(538)
Accumulated other comprehensive income	807	343
Retained earnings	112,554	57,979

Total stockholders equity	361,029	270,375
Total liabilities and stockholders equity	$ 411,082	$ 324,741

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		
	2004	2003	2002
Revenues:			
Product sales	$ 222,560	$ 188,645	$ 139,932
Collaborative research revenue	27,122	15,402	11,032
Royalty and license revenue	20,025	3,144	4,633
Total revenues	269,707	207,191	155,597
Operating expenses:			
Cost of product sales	59,908	45,458	53,411
Research and development	68,482	63,565	47,045
Marketing and sales	27,191	22,586	18,199
General and administrative	31,628	23,233	20,995
Total operating expenses	187,209	154,842	139,650
Income from operations	82,498	52,349	15,947
Other income (expense):			
Minority interest	(296)	(97)	
Interest income	2,815	2,415	906
Interest expense	(28)	(65)	(1,868)
Other income (expense), net	(410)	494	3,238
Total other income (expense)	2,081	2,747	2,276
Income before income taxes	84,579	55,096	18,223
Income tax expense	30,004	19,766	5,216
Net income	$ 54,575	$ 35,330	$ 13,007
Net income per share			
Basic	$ 1.10	$ 0.74	$ 0.27
Diluted	$ 1.06	$ 0.72	$ 0.27
Weighted average shares outstanding			
Basic	49,429	47,974	47,600
Diluted	51,403	49,137	47,610

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		
	2004	2003	2002
Operating activities			
Net income	$ 54,575	$ 35,330	$ 13,007
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	18,239	15,822	17,784
Stock compensation charges	1,142	149	
Loss on disposal of property and equipment	377	102	308
Deferred rent	(14)	(4)	30
Stock option income tax benefits	14,035	4,387	
Deferred revenue	2,119	(1,085)	1,221
Deferred income taxes	5,567	(2,239)	1,106
Minority interest	(13)	37	
Changes in assets and liabilities:			
Accounts receivable	(6,774)	(2,164)	6,219
Inventories	(13,621)	(688)	(753)
Prepaid expenses and other current assets	(3,761)	(5,089)	(531)
Accounts payable	(2,535)	310	58
Accrued salaries and employee benefits	242	2,710	1,920
Other accrued expenses	(2,329)	(259)	(1,059)
Income tax payable	(4,965)	5,297	2,927
Net cash provided by operating activities	62,284	52,616	42,237
Investing activities			
Proceeds from sales and maturities of short-term investments	159,301	42,722	
Purchases of short-term investments	(206,822)	(95,421)	(64,842)
Purchases of property, plant and equipment	(26,021)	(12,238)	(12,616)
Capitalization of license fees	(19,026)	(3,000)	
Capitalization of software development costs	(270)	(2,070)	(3,011)
Capitalization of patent costs	(540)	(635)	(678)
Cash paid for acquisition of Molecular Light Technology shares, net of cash acquired	(376)	(4,133)	
Other assets	42	(12)	400
Net cash used in investing activities	(93,712)	(74,787)	(80,747)
Financing activities			
Proceeds from issuance of common stock	20,438	14,888	
Principal payments on long-term debt			(12,000)
Capital contribution from merger with Gen-Probe Holding			75,878

Net cash provided by financing activities	20,438	14,888	63,878
Effect of exchange rate changes on cash	515	138	
Net increase (decrease) in cash and cash equivalents	(10,475)	(7,145)	25,368
Cash and cash equivalents at the beginning of year	35,973	43,118	17,750
Cash and cash equivalents at the end of year	$ 25,498	$ 35,973	$ 43,118
Supplemental disclosure of cash flow information:			
Cash paid for:			
Interest	$ 34	$ 63	$ 754
Income taxes	$ 16,030	$ 11,913	$ 2,104
Non-cash financing activities:			
Contribution of non-cash items from merger with Gen-Probe Holding	$	$	$ 10,646

See accompanying notes to consolidated financial statements.

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

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders Equity
Balance at December 31, 2001	47,600	$ 5	$ 106,100	$	$ 60	$ 9,642	$ 115,807
Capital contribution from merger with Gen-Probe Holding			86,524				86,524
Comprehensive income:							
Net income						13,007	13,007
Unrealized gains on short-term investments, net of income tax expense of $53					240		240
Comprehensive income							13,247
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 restricted stock awards			839	(839)			
Amortization of deferred compensation				273			273
Stock option compensation expense for modification of stock option awards			729				729
Stock option income tax benefits			14,035				14,035
Comprehensive income:							
Net income						54,575	54,575
Unrealized losses on short-term investments, net of income tax benefits of $17					(313)		(313)
Foreign currency translation adjustment					777		777
Comprehensive income							55,039
Balance at December 31, 2004	50,035	$ 5	$ 248,767	$ (1,104)	$ 807	$ 112,554	$ 361,029

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 for screening donated human blood. Gen-Probe s principal customers are large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

These consolidated financial statements reflect the Company s historical financial results as an independent company, separate from the Company s former direct parent, Gen-Probe Holding Company, Inc. (Gen-Probe Holding), which was a wholly-owned subsidiary of Chugai Pharmaceutical, Co. Ltd. (Chugai) of Tokyo, Japan until the spin-off in September 2002.

In August 2003, the Company paid approximately $7.2 million 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 3.42% of the outstanding shares, giving the Company a total ownership of 86% when added to the amount previously held. As such, the Company owns more than 50% and has the ability to control the operations of this subsidiary and, therefore, has consolidated MLT with the Company since August 2003. MLT is a biotechnology company from which Gen-Probe licenses chemiluminescent technology it uses in its Hybridization Protection Assay (HPA) and dual kenetic assay (DKA). Gen-Probe is the exclusive licensee of the MLT technology for disease testing using nucleic acid hybridization. The acquisition was accounted for under the purchase method of accounting in accordance with Statement of Financial Accounting Standards (SFAS) No. 141 Business Combinations.

The remaining interest in MLT not owned by the Company is owned by two members of MLT s management and has been recorded as minority interest on the balance sheet and statement of income. As a condition to the acquisition, the Company entered into an option agreement which gives these individuals the option to sell to the Company their respective interests in MLT during a five-year period at a fixed price of approximately $958,000, plus accrued interest. The Company has the right to accelerate the purchase of these interests.

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 Canada, Inc., Gen-Probe UK Limited and Molecular Light Technology Limited 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.

Reporting periods

The Company historically has operated and reported on fiscal periods ending on the Friday closest to the end of the month except for year-end, which has closed on December 31. For ease of presentation, the quarterly reporting periods are deemed to end on March 31, June 30 and September 30. The fiscal years ended December 31, 2004, 2003 and 2002 each included 52 weeks. Beginning in 2005, coinciding with the Company s implementation of a new Enterprise Resource Planning system, the Company s fiscal quarters will end on March 31, June 30, September 30 and December 31.

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

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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, valuation of inventories and long-lived assets. Actual results could differ from those estimates.

Foreign currencies

The functional currency of the Company s majority owned subsidiaries, GPUK 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 these subsidiary s financial statements are recorded directly as a separate component of stockholders equity under the caption Accumulated other comprehensive income.

Cash and cash equivalents

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

Short-term investments

Short-term investments are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment and interest income. Realized gains and losses and declines in value judged to be other-than-temporary on short-term investments are included in investment and interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Segment information

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

Concentration of credit risk

The Company sells its 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 which 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 mortgage-backed securities, investment-grade corporate and municipal 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.

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

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 Company s ability to make payments, additional allowances would be required.

Stock-based compensation

The Company records compensation expense for employee stock-based compensation using their intrinsic value on the date of grant pursuant to Accounting Principles Board Opinion 25 (APB) No. 25, Accounting for Stock Issued to Employees. Under the intrinsic value method, compensation cost for employee stock awards is recognized as the excess, if any, of the deemed fair value for financial reporting purposes of the Company s common stock on the date of grant over the amount an employee must pay to acquire the stock. Because the Company establishes the exercise price based on the fair market value of the Company s stock at the date of grant, the stock options have no intrinsic value upon grant, and therefore no expense is recorded. 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 strike price of the stock option) are not included in diluted earnings per share.

As required under SFAS No. 123, Accounting for Stock-Based Compensation, 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 stock option plan inception date in 2000 through September 15, 2002 and the Black-Scholes option-pricing model for all option grants made subsequent to that date. The following weighted average assumptions were used:

	Stock Option Plans			ESPP		
	2004	2003	2002	2004	2003	2002
Risk-free interest rate	3.18%	2.76%	3.82%	1.04%	1.0%	
Volatility	63%	47%	72%*	60%	54%	
Dividend yield	0	0	0	0	0	
Expected life (years)	4.0	4.0	4.0	0.5	0.2	
Resulting average fair value	$ 18.83	$ 10.78	$ 0.91	$ 5.47	$ 1.80	

* Amount represents the average volatility for options granted from September 16, 2002 to December 31, 2002. From January 1, 2002 to September 15, 2002, the Company assumed no volatility pursuant to the minimum value method.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no restrictions and are fully transferable and negotiable in a free trading market. The Black-Scholes model does not consider the employment, transfer or vesting restrictions that are inherent in the Company s employee stock options. Use of an option valuation model, as required by SFAS No. 123, includes highly subjective assumptions based on long-term predictions, including the expected stock price volatility and average life of each stock option grant.

The fair value of each purchase right issued under the Company s Employee Stock Purchase Plan (ESPP) for the years ended December 31, 2004 and 2003 was estimated on the date of grant using the Black-Scholes pricing model. The Company did not have an employee stock purchase plan during the year ended December 31, 2002.

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

Had compensation expense for stock options granted been determined based on the fair value of the options 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		
	2004	2003	2002
Net income:			
As reported	$ 54,575	$ 35,330	$ 13,007
Stock-based employee compensation expense included in reported net income, net of related tax effects	590	37	
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(10,958)	(3,092)	(792)
Pro forma net income	$ 44,207	$ 32,275	$ 12,215
Net income per share:			
As reported			
Basic	$ 1.10	$ 0.74	$ 0.27
Diluted	$ 1.06	$ 0.72	$ 0.27
Pro forma			
Basic	$ 0.89	$ 0.67	$ 0.26
Diluted	$ 0.86	$ 0.66	$ 0.26

The pro forma effects on net income for the years ended December 31, 2004, 2003 and 2002 are not likely to be representative of the effects on reported net income in future years. Option valuation models require the input of highly subjective assumptions, and changes in such subjective assumptions can materially affect the fair value estimate of employee stock options.

Deferred compensation for restricted stock awards issued to the Company s chief executive officer has been determined in accordance with SFAS No. 123 as the fair value of the consideration received and is being amortized to expense on a straight-line basis over the vesting period. 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.

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 its collaboration partner, the Company s ultimate share of the net revenue from sales to the end user is not known until reported by its collaboration partner.

The Company manufactures its blood screening products according to Chiron s demand specifications and transfer/shipments of completed product to Chiron s virtual warehouse, which consists of various interim locations on Gen-Probe s premises. Upon transfer/shipment of completed product to Chiron s virtual warehouse, the Company bills Chiron at a cost recovery transfer price, and Chiron remits payment in 30 days. The Company records amounts billed

as deferred revenue until shipment to Chiron s end-customers. Customer orders for the assay are received by Chiron and then communicated to Company personnel who

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

fulfill the orders and ship to Chiron s end-customers. Upon shipment to the end-customer, the Company recognizes blood screening product sales at the cost recovery transfer price and records cost of products sold at the cost of the assays. Blood screening product sales are adjusted upon the Company s receipt of payment from Chiron of amounts reflecting its ultimate share of net sales by Chiron of these products, less the cost recovery transfer price revenues previously paid.

Product sales also include the sales or rental revenue associated with the delivery of the Company s proprietary instrument platforms that perform its diagnostic tests. Generally, the Company provides its instrumentation to clinical laboratories and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, the Company recovers the cost of providing the instrumentation in the amounts it charges for its diagnostic assays. The Company also has implemented multi-year sales contracts that have an equipment factor set forth in them. The costs associated with the instrument are charged to costs of product sales on a straight-line basis over the estimated life of the instrument, which ranges from three to five years; generally, three years for luminometers and DTS 400/800 systems, and five years for TIGRIS and DTS 800/1600 instruments. The costs to maintain these systems in the field are charged to cost of sales as incurred.

The Company sells its instrumentation 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 their customers. Occasionally, the Company sells instrumentation to its clinical diagnostics customers. The Company records sales of these instruments as product sales upon delivery and customer acceptance. Prior to delivery, each instrument is extensively tested to meet Company and 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 approval in foreign countries. Once commercial pricing is implemented, the Company then 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 that agreement. 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 and (iii) the fees are non-refundable. 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 arrangements 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.

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

Cost of revenues

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

The Company does not separately track the total 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 operations 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 $2,569,000, $2,258,000, and $1,780,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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, 2004 and 2003, capitalized patent costs, which have been included in Other assets on the consolidated balance sheet, totaled approximately $1,243,000 and $1,691,000, 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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GEN-PROBE INCORPORATED
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 is provided using the straight-line method over the estimated useful lives of the assets as follows:

	Years
Building	10-39
Machinery and equipment	3-5
Furniture and fixtures	3

Depreciation expense was $14,497,000, $14,380,000 and $15,632,000 for the years ended December 31, 2004, 2003 and 2002, 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. Goodwill less the amount allocated to in-process technology was being amortized over 40 years through December 31, 2001.

Impairment of long-lived assets

The Company adopted SFAS No. 142, Goodwill and Other Intangible Assets, at the beginning of 2002, which prohibits the amortization of 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 2004 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, 2004.

Self-insurance reserves

The Company s consolidated balance sheets at December 31, 2004 and 2003 include approximately $1,402,000 and $694,000 of liabilities with respect to the portion of employee benefit costs which are retained by the Company, including medical costs and workers compensation claims. The Company estimates the required liability of such claims on an undiscounted basis utilizing an actuarial method that is based upon various assumptions which include, but are not limited to, the Company s historical loss experience and projected loss development factors. The required liability is also subject to adjustment in the future based upon the changes in claims experience, including changes in the number of incidents (frequency) and change in the ultimate cost per incident (severity).

Accumulated other comprehensive income

In accordance with SFAS No. 130, Reporting Comprehensive Income, all components of comprehensive income, including net income, are reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, which includes certain changes in stockholders equity such as foreign currency translation of our majority owned subsidiary s financial statements and unrealized gains and losses on our available-for-sale securities, are reported, net of their related tax effect, to arrive at comprehensive income.

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GEN-PROBE INCORPORATED
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Research and development

Research and development costs are expensed as incurred.

Income taxes

Through December 31, 2002, the Company was included in the consolidated federal and in various combined state income tax returns of its former parent company, Gen-Probe Holding, Inc. (formerly known as Chugai Pharma U.S.A., Inc. or CPUSA). Pursuant to a tax-sharing agreement with Gen-Probe Holding, the Company was generally allocated an amount of the consolidated tax liability equal to the tax that would have been applicable if computed separately.

Under this agreement, any deductible amounts allocated to the Company and not allocated back to Gen-Probe Holding were deemed to be a capital contribution by Gen-Probe Holding at the end of each year. In connection with the reorganization and spin-off, Gen-Probe Holding merged into the Company and the Company entered into a new tax-sharing agreement with CPUSA.

The tax benefit for stock options is calculated by determining the estimated tax liability with and without stock compensation deductions. Certain tax credits if limited by income, are calculated using the estimated tax liability including the stock compensation deductions in both calculations. The Company records the difference between these two calculations to income taxes payable and additional paid in-capital.

It is our policy to establish reserves based upon management s assessment of exposure for tax credits claimed in previously filed tax returns that may become payable upon audit by tax authorities. The tax reserves are analyzed at least annually, generally in the fourth quarter of each year, and adjustments are made as events occur which warrant adjustments to the reserve.

Reclassifications

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

Recent accounting pronouncement

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB No. 25, and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of income based on their fair values. Pro forma disclosure is no longer an alternative. The Company is required to adopt Statement 123(R) on July 1, 2005.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB No. 25 s intrinsic value method and, as such, generally recognizes 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 will have no 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 literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While the Company cannot estimate what those amounts will

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

be in the future (because they depend on, among other things, when employees exercise stock options), the amount of operating cash flows recognized in prior periods for such excess tax deductions were $14,035,000, $4,387,000, and $0 for the years ended December 31, 2004, 2003 and 2002, respectively.

Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share, and SEC Staff Accounting Bulletin (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.

Under the provisions of SAB No. 98, common shares issued for nominal consideration, if any, would be included in the per share calculations as if they were outstanding for all periods presented. The Company considers common equivalent shares from the exercise of stock options in the instance where the shares are dilutive to net income of the Company by application of the treasury stock method.

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

	December 31		
	2004	2003	2002
Net income	$ 54,575	$ 35,330	$ 13,007
Weighted average shares outstanding Basic	49,429	47,974	47,600
Effect of dilutive common stock options outstanding	1,974	1,163	10
Weighted average shares outstanding Diluted	51,403	49,137	47,610
Net income per share:			
Basic	$ 1.10	$ 0.74	$ 0.27
Diluted	$ 1.06	$ 0.72	$ 0.27

Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 244,296, 1,470,911 and 2,349,192 for the years ended December 31, 2004, 2003 and 2002, respectively were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

2. Balance sheet information

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

Inventories

	December 31	
	2004	2003
Raw materials and supplies	$ 5,345	$ 5,874
Work in process	10,429	3,118
Finished goods	11,534	4,684

	$ 27,308	$ 13,676

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property, plant and equipment

	December 31	
	2004	2003
Land	$ 9,100	$ 9,100
Building	40,593	40,534
Machinery and equipment	93,337	86,717
Leasehold improvements	15,907	17,181
Furniture and fixtures	9,874	9,393
Construction in-progress	8,775	2,149
Property, plant and equipment (at cost)	177,586	165,074
Less accumulated depreciation and amortization	(100,935)	(99,596)
Property, plant and equipment (net)	$ 76,651	$ 65,478

Other assets

	December 31	
	2004	2003
Patents and other intangible assets	$ 15,305	$ 14,764
Purchased intangible assets	33,636	33,636
License fees	22,026	3,000
Other	236	260
	71,203	51,660
Less accumulated amortization	(46,808)	(44,767)
	$ 24,395	$ 6,893

As of December 31, 2004, the Company has capitalized $23,466,000, net in software costs associated with the development of the TIGRIS instrument. In addition, the Company has an aggregate of $16,910,000 in TIGRIS-related items consisting of inventories, machinery and equipment and prepaid expenses.

3. Short-term investments

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

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value

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

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

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2004, by contractual maturity, are as follows (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Maturities				
Within one year	$ 50,139	$	$ (150)	$ 49,989
After one year through five years	118,151	391	(203)	118,339
Total short-term investments	$ 168,290	$ 391	$ (353)	$ 168,328

The following is a summary of short-term investments as of December 31, 2003 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate obligations	$ 18,745	$ 122	$	$ 18,867
Mortgage backed government securities	41,909	72	(1)	41,980
Municipal securities	59,327	171	(12)	59,486
Total short-term investments	$ 119,981	$ 365	$ (13)	$ 120,333

Gross realized gains from the sales of short-term investments were $402,000 for the year ended December 31, 2004. Gross realized losses from the sales of short-term investments were $693,000 for the year ended December 31, 2004. Realized gains and losses were not significant for the years ended December 31, 2003 and 2002.

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					
	2004			2003		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	$ 25,142	$ 1,676	$ 23,466	$ 24,872	$	$ 24,872
Patents	15,305	14,062	1,243	14,764	13,073	1,691
Purchased intangible assets	33,636	31,994	1,642	33,636	31,658	1,978

License fees	22,026	752	21,274	3,000	36	2,964
Total	$ 96,109	$ 48,484	$ 47,625	$ 76,272	$ 44,767	$ 31,505
Goodwill	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621

In September 2004, the Company entered into a Settlement Agreement and an Amendment to its Non-exclusive License Agreement with Vysis Inc. (Vysis) under which the Company has withdrawn its patent litigation against Vysis and agreed to pay Vysis an aggregate of $22,500,000. This aggregate amount includes

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

$20,500,000 for a fully paid up license to eliminate all future royalty obligations of the Company to Vysis under the Collins patent covered by the license, and $2,000,000 for a fully paid-up, royalty-free license in additional fields covered by the Collins patent. The license now covers current and future products in the field of infectious diseases as well as potential products in all other fields. Chiron, the Company s blood screening partner has reimbursed the Company $5,474,000 of the $20,500,000 allocated to the cost of the fully paid-up license for the current field, commensurate with its obligation to reimburse the Company a portion of the royalties paid by the Company to Vysis on blood screening products. The Company capitalized the $17,026,000 net payment ($22,500,000 less Chiron s $5,474,000 reimbursement) as an intangible asset which is being amortized to cost of goods sold over the patent s remaining economic life of 135 months.

The Company had aggregate amortization expense of $3,717,000, $1,442,000 and $2,194,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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

Years Ended December 31	Amortization Expense
2005	$ 5,969
2006	5,086
2007	4,834
2008	4,729
2009	4,675
Thereafter	22,332
Total	$ 47,625

5. Long-term debt

In 1997, the Company issued $14,000,000 of notes payable to a bank and an insurance company. The notes bore interest at 7.68%, with interest payable through December 31, 2000, then principal and interest through May 2007.

In September 2002, in connection with the Company s spin-off from Chugai, the Company repaid in full the remaining $10,000,000 of principal due on the notes, the accrued interest due and a prepayment premium of approximately $1,200,000. The prepayment premium and the remaining deferred financing fees associated with the notes totaled $1,250,000 and were previously recorded as a $750,000 extraordinary loss ($1,250,000 charge, net of a $500,000 tax benefit) in the consolidated financial statements. The Company adopted SFAS No. 145 in 2003 and reclassified the prepayment premium and the deferred financing fees associated with the early pay-off of debt recorded in the third quarter of 2002, from an extraordinary loss to interest expense on the statement of income. The tax benefit has been reflected as a component of income tax expense. The reported net income did not change.

The Company has secured a bank line of credit agreement, which expires in July 2005, under which the Company may borrow up to $10,000,000 at the bank s prime rate, or at LIBOR plus 1%. The line of credit is secured by the assets of the Company other than real property. At December 31, 2004, the Company did not have any amounts outstanding under the line. The line of credit agreement requires the Company to comply with various financial covenants. Financial covenants include requirements as to tangible net worth, liabilities as a percentage of tangible net worth, the ratio of current assets to current liabilities, required minimum levels of earnings before interest, taxes, depreciation and amortization, and the ratio of funded debt to earnings

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

before interest, taxes, depreciation and amortization. The Company was in compliance with all covenants at December 31, 2004.

6. Related party transactions

The Company recorded royalty expense to MLT of $1,451,000 and $2,467,000 for the years ended December 31, 2003 and 2002, respectively, 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.

7. Income taxes

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

	Years Ended December 31		
	2004	2003	2002
Current:			
Federal	$ 22,499	$ 20,316	$ 3,788
International	202	500	127
State	1,589	1,264	238
	24,290	22,080	4,153
Deferred:			
Federal	3,389	(3,443)	1,524
International	(114)	219	
State	2,439	910	(461)
	5,714	(2,314)	1,063
	$ 30,004	$ 19,766	$ 5,216

The provision for income taxes varies from the amount computed by applying the federal statutory rate to income before income taxes due to the nondeductibility of the amortization of goodwill and certain other intangible assets for tax reporting purposes, less certain tax credits realized and tax exempt foreign income.

The Company has not provided for United States income taxes on foreign subsidiaries undistributed earnings of approximately $6,000,000 at December 31, 2004, which are expected to be reinvested indefinitely outside the United States. It is not possible to predict the amount of United States income taxes that might be payable if these earnings were eventually repatriated.

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

	December 31	
	2004	2003
Deferred tax assets:		
Research and California manufacturers investment credit carryforwards	$ 3,025	$ 4,457
Inventory reserves and capitalization	5,075	8,333
Allowance for doubtful accounts	280	302
Deferred revenue	2,238	2,498
Depreciation		376
Other accruals and reserves (net)	2,021	1,932
Total deferred tax assets	12,639	17,898
Valuation allowance	(3,019)	(2,847)
Total net deferred tax assets	9,620	15,051
Deferred tax liabilities:		
Purchased intangibles	(638)	(769)
Capitalized costs expensed for tax purposes	(8,927)	(10,153)
Depreciation	(1,517)	
Total net deferred tax liabilities	(11,082)	(10,922)
Net deferred tax assets (liabilities)	$ (1,462)	$ 4,129

In connection with the merger of Gen-Probe Holding into Gen-Probe, the Company recorded approximately $2,847,000 of deferred tax assets. These deferred tax assets relate principally to financial statement depreciation in excess of that deducted for tax purposes and to research and development tax credits previously held by CPUSA, the successor to the Company s sister company, Chugai Biopharmaceuticals, Inc., which have been included in the combined tax returns of the Company. These deferred tax assets are being carried forward and may be realized in future periods depending on, among other factors, the Company s having sufficient taxable income in the future periods. The deferred tax assets recorded are fully offset by a valuation reserve until these deductions and credits are realized.

The Company has also recorded a deferred tax asset of approximately $172,000 for foreign tax credits, which has been fully offset by a valuation reserve until the Company determines that it will be able to claim the credits. Other than the valuation allowance for the net deferred tax assets from CPUSA and the foreign tax credit, no additional valuation allowance has been recorded to offset deferred tax assets as the Company has determined that it is more likely than not that such assets will be realized. The Company will continue to assess the likelihood of realization of such assets; however, if future events occur which do not make the realization of such assets more likely than not, the Company will record a valuation allowance against all or a portion of the net deferred tax assets.

At December 31, 2004, the Company also had California research and development credit carryforwards of approximately $3,716,000, which do not expire. In accordance with the Internal Revenue Code, the Company s use of

its credit carryforwards could be limited in the event of certain cumulative changes in the Company s stock ownership.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31					
	2004	2003	2002	2004	2003	2002
Expected income tax provision at federal statutory rate	$ 29,603	$ 19,305	$ 6,378	35 %	35 %	35 %
State income tax provision, net of federal benefit	3,653	2,356	723	4 %	5 %	4 %
Federal tax credit	(1,500)	(1,500)	(1,000)	(2)%	(3)%	(5)%
State tax credits	(975)	(943)	(943)	(1)%	(2)%	(5)%
Other	(777)	548	58	(1)%	1 %	%
Actual income tax provision	$ 30,004	$ 19,766	$ 5,216	35 %	36 %	29 %

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

8. Stockholders equity

On May 28, 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.

The merger of Gen-Probe Holding into Gen-Probe on July 23, 2002 was reflected as a reorganization of entities under common control and the assets and liabilities were recorded at the historical book value at the merger date. Gen-Probe did not issue additional shares of its common stock in excess of the number of shares previously owned by Gen-Probe Holding to Chugai in consideration for the net assets acquired. Instead, Gen-Probe adjusted all outstanding options to purchase its common stock granted under its 2000 Equity Participation Plan. The number of shares subject to each option was reduced by approximately 17.6% to recognize the contribution of the net assets to Gen-Probe through the merger of Gen-Probe Holding into Gen-Probe. Although the adjustment resulted in a reduction in option holders aggregate ownership stake in Gen-Probe relative to Chugai s ownership stake, the reduction was in proportion to the reduction that would have resulted from the issuance by Gen-Probe of additional shares of Gen-Probe common stock to Chugai in connection with the merger had such shares actually been issued. The results of operations of Gen-Probe Holding are included in the accompanying consolidated financial statements beginning on July 23, 2002.

The net assets from Gen-Probe Holding acquired were as follows (in thousands):

Cash and cash equivalents	$ 75,878
Land and land improvements	9,100
Goodwill	1,397
Other assets, net	149
Net assets acquired	$ 86,524

Gen-Probe s lease of the land on which its headquarters is located terminated automatically upon the completion of the merger on July 23, 2002 because Gen-Probe now owns the land.

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On September 16, 2002, the Company adopted a stockholder rights plan that could discourage, delay or prevent an acquisition of the Company under certain circumstances. The plan was amended by the Board of Directors on November 20, 2003. 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. 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 outstanding at the close of business on September 26, 2002, which automatically adjusted to one-half of a right as a result of the 100% stock dividend paid by the Company on September 30, 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 initial distribution of rights is expected to be non-dilutive and non-taxable to stockholders for United States federal income tax purposes.

In each of June 2004 and August 2003, the Company granted 20,000 shares of restricted stock units to its chief executive officer under The 2003 Incentive Award Plan of Gen-Probe Incorporated (the 2003 Plan), resulting in deferred compensation of $839,000 and $600,000, respectively, associated with these grants. The deferred compensation is being amortized to expense over the vesting period (48 months) of the restricted stock units. The Company also issued 3,660 and 3,718 shares of common stock under the 2003 Plan during the years ended December 31, 2004 and 2003, to members of the Board of Directors as partial consideration for services rendered, resulting in an expense totaling $140,663 and $86,710, respectively, which was equal to the fair market value on the date of grants.

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 Plan provides for incentives for officers, directors, employees and consultants through the granting of incentive and nonstatutory 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 nonstatutory 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

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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. All share amounts presented below for the 2000 Plan have been adjusted to reflect the reduction by approximately 17.6% for the contribution of cash and land to Gen-Probe through the merger of Gen-Probe Holding into Gen-Probe in July 2002.

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, 2001	3,604,116	$ 13.36
Granted	1,618,998	12.12
Exercised		
Cancelled	(545,022)	13.39
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

The following table summarizes information about stock options outstanding at December 31, 2004:

	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	1,262,504	7.2	$ 11.81	658,840	$ 11.72
$13.50 - $15.51	1,211,828	6.0	13.70	1,040,870	13.67
$19.19 - $29.53	1,327,779	8.6	28.47	429,393	28.31
$30.68 - $36.47	564,198	9.0	33.87	49,297	32.26
$36.59	1,196,000	9.6	36.59		
$37.42 - $47.32	441,745	9.4	41.03	29,994	41.94

6,004,054	8.1	$	25.03	2,208,394	$ 16.73

Shares of common stock available for future grants under all stock option plans were 1,915,224 at December 31, 2004.

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

	Years Ended December 31		
	2004	2003	2002
Exercise price equal to the fair value of common stock on the grant date:			
Weighted-average exercise price	$ 37.21	$ 27.19	$ 8.68
Weighted-average option fair value	$ 18.83	$ 10.78	$ 4.41
Exercise price greater than deemed fair value of common stock on the grant date:			
Weighted-average exercise price	$	$	$ 12.66
Weighted-average option fair value	$	$	$ 0.17

Employee stock purchase plan

In May 2003, the Company adopted 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 Stock Split. The ESPP is intended to qualify under Section 423 of the Internal Revenue 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 $21,250 per calendar year, withheld through payroll deductions to purchase shares of common stock under the ESPP. The purchase price of the common stock purchased under the ESPP is equal to 85% of the fair market value of the common stock on the offering or Grant Date or the exercise or purchase date, whichever is lower. During the years ended December 31, 2004 and 2003, employees purchased 132,218 and 34,714 shares at an average price of $28.49 and $16.91 per share, respectively. As of December 31, 2004, 833,068 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 February 2008. Future minimum payments under operating leases as of December 31, 2004 are as follows (in thousands):

2005	$ 2,422
2006	1,762
2007	765
2008	96
Total payments	$ 5,045

Rent expense was $2,626,000, $1,700,000 and $1,727,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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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 has 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 a licensing agreement with certain performance obligations. In exchange for the royalties paid under the original agreement, Gen-Probe transferred all information and know-how to bMx as of December 31, 2000. Additionally, the Company transferred all products, work instructions, formulations and necessary materials needed for manufacturing key biochemistry components under the agreements to bMx by January 1, 2003, except that we continued to manufacture two enzyme formulations through July 15, 2003. Gen-Probe records revenue under this arrangement when specific milestones are achieved. Gen-Probe recognized milestone revenue of $1,250,000 for the year ended December 31, 2002. In addition, the Company recognized $1,870,000 in license fees related to this agreement for the year ended December 31, 2002. During the years ended December 31, 2004 and 2003, Gen-Probe recognized $600,000 and $750,000 in minimum annual royalties, respectively.

In September 2004, the Company signed non-exclusive licensing agreements with bioMérieux and its affiliates that provide bioMérieux options to access the Company s ribosomal RNA technologies for certain uses, and that give the Company access to bioMérieux s intellectual property for detecting genetic mutations that predispose people to blood clotting disorders. Under the terms of the agreements, bioMérieux paid the Company $250,000 for limited non-exclusive research licenses and options to develop products for certain targets using our patented ribosomal RNA technologies. BioMérieux also terminated its license agreements with the Company relating to the development of assays for bioMérieux s VIDAS instrument. Further, the Company obtained from bioMérieux a non-exclusive, worldwide license to use bioMérieux s intellectual property to develop tests that detect mutations in the genes that code for factor V and prothrombin, proteins that control the blood clotting process. The Company will also pay bioMérieux royalties on the sale of any products developed using bioMérieux s intellectual property. In connection with the VIDAS termination and the license of factor V and prothrombin rights, the Company recorded net revenue of $100,000. The amount of revenue that Gen-Probe will record in the future related to these non-exclusive licensing agreements will depend on the number of targets selected by bioMérieux.

In July 1998, the Company entered into an agreement with Chiron Corporation (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 immune deficiency 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 agreed to sell its diagnostic business to Bayer. As a result, the Company and Bayer have aligned under the terms of the agreement relating to clinical diagnostics. The Company recorded licensing revenues of approximately $670,000 from Chiron for each of the years ended December 31, 2004, 2003 and 2002, 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 Federal Drug Administration (FDA) approval of the Procleix Ultrio assay.

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In connection with its collaboration agreement with Chiron, the Company developed and supplied products to the American Red Cross, America s Blood Centers, American Independent Blood Centers, the United States military and others for pooled blood sampling under the terms of an Investigational New Drug (IND). The Company received monthly payments for costs that were incurred for development of the product. The contracts terminated upon commercial release of the product in the United States in 2002. Collaborative research revenue recorded under the terms of the agreements for the year ended December 31, 2002 was $7,100,0000. 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. In addition, for the years ended December 31, 2004 and 2003, the Company recognized $18,543,000 and $5,962,000 in collaborative research revenue through its collaboration with Chiron from deliveries of West Nile virus (WNV) tests on a cost recovery basis. The Company expects to continue recognizing these sales as collaborative research revenue until such time as FDA approval has been received.

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 written agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. During the years ended December 31, 2004 and 2003, the Company received $2,766,000 and $3,932,000, respectively, in reimbursements for expenses incurred related to the development of the Procleix Ultrio assay from Chiron. The Procleix Ultrio assay, and the discriminatory assays that will be used in conjunction with it, will be marketed by Chiron under the tradename Procleix Ultrio assay. In January 2004, the Company commenced clinical trials of the Procleix Ultrio assay in the United States on its TIGRIS instrument. In September 2004, the Company filed a Biologics License Application (BLA) with the FDA for this assay. The Company has also developed a NAT assay to detect WNV, which is currently being used in clinical trials under an IND application. The Company expects to receive further reimbursement from Chiron for certain costs incurred during the development of the Procleix Ultrio and WNV assays.

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 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.

Under the strategic alliance agreement the Company entered into with Chiron in June 1998, the Company has 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 the first quarter of 2004, the Company recognized as royalty and license revenue, a $6,500,000 milestone payment, as the Company began clinical trial tests of the Procleix Ultrio assay on the TIGRIS instrument in the United States. Additional payments of up to $10,000,000 are due to the Company in the future under the agreement if they achieve certain other specified milestones relating to

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the development of the TIGRIS instrument. There is no guarantee they will receive any additional milestone payments under this agreement.

License agreements

In connection with its research and development efforts, the Company has various license agreements with unrelated parties which 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 an agreement 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 agreement, Tosoh received non-exclusive rights to the Company s proprietary Transcription-Mediated Amplification, or 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, or TRC, amplification and Intercalation Activating Fluorescence, or INAF, detection technologies for use with their real time TMA technology.

During 1995, the Company granted to Becton Dickinson a non-exclusive license to certain patented methods for detecting specific infectious diseases. In exchange for this license, Gen-Probe received a license fee and will receive a royalty on all sales of licensed products under the agreement. Royalties received from Becton Dickinson amounted to $653,000, $569,000 and $494,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Government contract

In January 2000, the Company began work on a three-year $13,400,000 cost sharing contract with the NIH, to modify the Procleix HIV-1/ HCV assay to incorporate HBV detection capability and make it simpler for organ donation centers to test the blood of organ donors. Under the terms of the agreement, the NIH will reimburse the Company $7,800,000. The Company recorded contract revenues under the reimbursement contract as costs were incurred. Costs incurred were recorded in research and development expenses. Contract revenues recorded for the year ended December 31, 2002 were $3,067,000. Billings under the contract were completed in 2002.

The Company received a $1,000,000 contract extension from the NIH in October of 2002 to develop a NAT assay for the detection of the WNV. This amount was further increased by an additional $2,470,000 in February 2003. In addition, in February 2003, the Company filed for an IND covering the WNV. Contract revenues recorded under these extensions were $3,470,000 for the year ended December 31, 2003. Billings under these contract extensions were completed in September 2003.

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 our nucleic acid test 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. As of July 2004, the Company had billed and collected all monies under this contract.

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Litigation

The Company is a party to the following litigation and may participate 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. Enzo has asserted a damage claim based on a contention that Enzo was entitled to a reasonable royalty on all sales of Gen-Probe products for the detection of *Neisseria gonorrhoeae* bacteria from June 1993 through trial. Revenues from tests for the detection of *Neisseria gonorrhoeae* have constituted a significant portion of Gen-Probe s revenues during the relevant period. The Company believes that the claims of the 659 patent are invalid, unenforceable and may not be properly interpreted to cover its products. On July 27, 2004, the Court granted summary judgment in favor of the defendants and against Enzo, holding that the 659 patent is invalid based on the on-sale doctrine. Enzo has appealed the summary judgment to the United States Court of Appeals for the Federal Circuit. The parties have not yet completed their submissions of briefs to the Court of Appeals. The Company intends to vigorously defend the lawsuit. However, there can be no assurance that the case will be resolved in the Company s favor.

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 collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of 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 seeks 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 has also been 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. The arbitrator agreed to review additional written testimony following closing arguments, and has informed the parties that he intends to issue a written decision on or about March 25, 2005. There can be no assurances as to the final outcome of the arbitration.

On March 17, 2004, the Company filed a patent infringement action in the United States District Court for the Southern District of California against Bayer Corporation and Bayer Healthcare LLC, alleging 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. Bayer s bDNA tests are not covered by the collaboration agreement between the companies. Bayer has denied the allegations of

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infringement and alleged that the patent is invalid or unenforceable. No trial date has been set. There can be no assurances as to the final outcome of the litigation.

Other

The Company is obligated to purchase raw materials used in manufacturing and instrumentation from two key vendors. The minimum purchase commitment is approximately $15,085,000 for the year ended December 31, 2005.

10. Significant customers and geographic information

During the years ended December 31, 2004, 2003 and 2002, 47%, 42% and 30%, 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, 2004, 2003 and 2002, 43%, 41% and 27%, 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, Collaborative Agreements. During the years ended December 31, 2004, 2003 and 2002, 57%, 59% and 73%, 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		
	2004	2003	2002
Total revenue:			
North America	$ 224,607	$ 180,924	$ 132,355
Rest of World	45,100	26,267	23,242
	$ 269,707	$ 207,191	$ 155,597

11. Employee benefit plan

Effective May 1, 1990, Gen-Probe established a Defined Contribution Plan (the Plan) covering substantially all employees of Gen-Probe Incorporated 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 $1,332,000, $1,110,000 and $985,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

12. Quarterly information (unaudited)

The following tables set forth the quarterly results of operations for each quarter within the two-year period ended December 31, 2004 (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 our audited

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

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
2004				
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

	Quarter Ended			
	March 31	June 30	September 30	December 31
2003				
Total revenues	$ 46,168	$ 50,682	$ 52,281	$ 58,060
Cost of product sales	12,919	11,055	10,828	10,656
Total operating expenses	33,433	38,760	39,432	43,217
Net income	8,654	8,149	8,850	9,677
Net income per share:				
Basic	$ 0.18	$ 0.17	$ 0.18	$ 0.20
Diluted	$ 0.18	$ 0.17	$ 0.18	$ 0.19

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SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS
FOR THE THREE Years Ended December 31, 2004
(In thousands)

	Balance at Beginning of Period	Addition Charged to Cost and Expenses[1]	Deductions[2]	Balance at End of Period
Allowance for doubtful accounts:				
Year Ended December 31, 2004:	$ 717	$	$ (53)	$ 664
Year Ended December 31, 2003:	787	(48)	(22)	717
Year Ended December 31, 2002:	824	(10)	(27)	787
Inventory reserves:				
Year Ended December 31, 2004:	8,694	15,868	(15,495)	9,067
Year Ended December 31, 2003:	12,105	12,263	(15,674)	8,694
Year Ended December 31, 2002	14,060	4,115	(6,070)	12,105

(1) For inventory reserves, includes net favorable manufacturing variances capitalized against inventory.

(2) Represents amounts written off against the allowance or reserves; or for net favorable manufacturing variances, credited to cost of products sold.

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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.*

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Exhibit Number	Description
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.*
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.*

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Exhibit Number	Description
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.*
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	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.*

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Exhibit Number	Description
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	License Agreement between AdnaGen AG and Gen-Probe Incorporated effective as of December 30, 2004.**
10.67	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.
21.1(12)	List of subsidiaries of Gen-Probe Incorporated.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification dated March 15, 2005, 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 15, 2005, 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 15, 2005, 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 15, 2005, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

Filed herewith.

Indicates management contract or compensatory plan, contract or arrangement.

(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.

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(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) Incorporated by reference to Gen-Probe s Report on Form S-8 filed with the SEC on March 18, 2003.

(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

* 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.