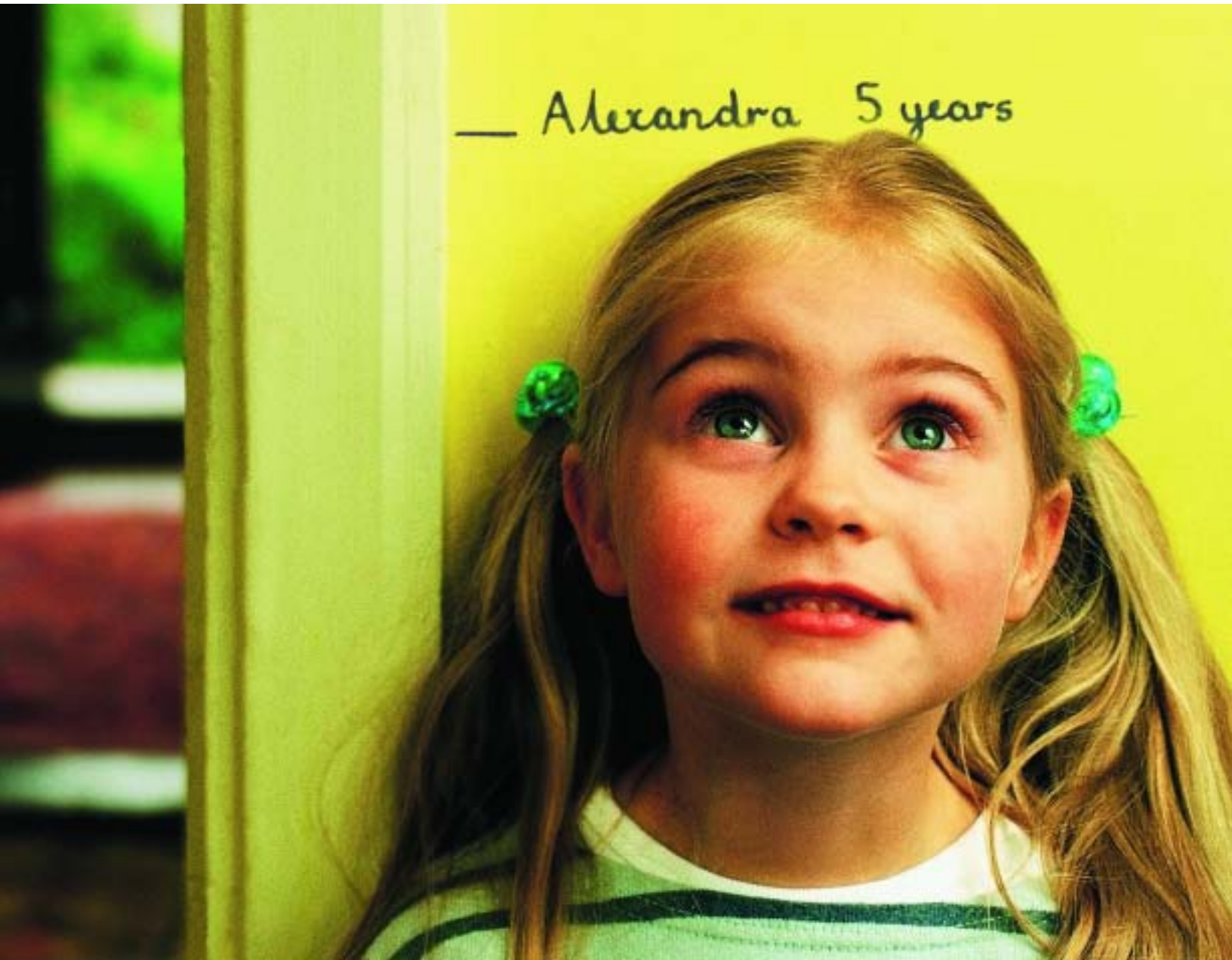
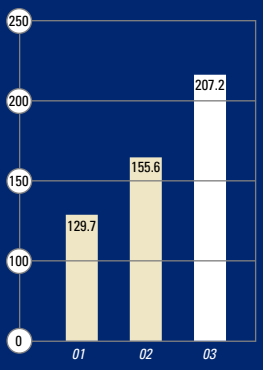
GEN-PROBE

Today's achievements, tomorrow's growth

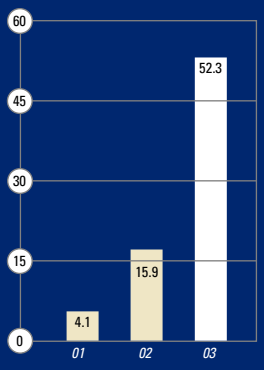
ANNUAL REPORT *2003*



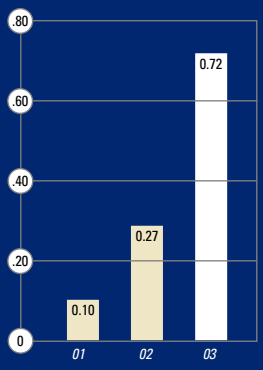
Gen-Probe (Nasdaq: GPRO) is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid testing products used for the clinical diagnosis of human diseases and for screening donated human blood.



TOTAL REVENUES
IN MILLIONS OF DOLLARS



OPERATING INCOME
IN MILLIONS OF DOLLARS



DILUTED EARNINGS PER SHARE
IN DOLLARS

Financial Highlights
IN THOUSANDS EXCEPT PER SHARE DATA

FOR THE YEARS ENDED DECEMBER 31,	2001	2002	2003
Income Statement			
Total revenues	$ 129,731	$ 155,597	**$ 207,191**
Product sales	$ 104,233	$ 139,932	**$ 188,645**
Research and development	$ 53,967	$ 46,709	**$ 63,193**
Operating income	$ 4,051	$ 15,947	**$ 52,349**
Net income	$ 4,617	$ 13,007	**$ 35,330**
Diluted earnings per share	$ 0.10	$ 0.27	**$ 0.72**
Balance Sheet			
Cash & short-term investments	$ 17,750	$ 107,960	**$ 156,306**
Total assets	$ 160,347	$ 258,157	**$ 324,741**
Long-term debt, including current portion	$ 12,000	$ 0	**$ 0**
Stockholders' equity	$ 115,807	$ 215,578	**$ 270,375**





2003 Achievements

June
Gen-Probe's investigational West Nile virus (WNV) blood screening assay becomes available for use by U.S. blood centers.

August
Gen-Probe acquires U.K.-based Molecular Light Technology in a financially accretive deal that provides a base for expansion into Europe and into industrial nucleic acid testing markets.

November
Gen-Probe acquires exclusive worldwide license to develop and market a new, highly specific genetic marker for prostate cancer called PCA3.

December
Gen-Probe begins U.S. clinical trials of the Procleix® Ultrio™ assay for the simultaneous detection of HIV-1, hepatitis C virus (HCV) and hepatitis B virus in donated blood.

December
Gen-Probe receives FDA clearance to run the APTIMA Combo 2® assay, which simultaneously detects chlamydial infections and gonorrhea, on the TIGRIS® DTS™ system, the first fully automated, high-throughput molecular diagnostic testing instrument.

2004 Goals

Increase market share of the APTIMA Combo 2 assay by running it on the new, revolutionary TIGRIS system.

Through marketing partner Chiron, drive international growth of the Procleix HIV-1/HCV and Procleix Ultrio blood screening assays.

File a Biologics License Application for FDA approval to commercialize the Procleix Ultrio assay on the semi-automated and TIGRIS instruments.

Introduce the WNV blood screening assay on the TIGRIS system under an investigational new drug application in the United States.

Achieve strong growth in revenues and earnings per share consistent with financial guidance.

Dear Fellow Shareholders,

2003 was an excellent year for Gen-Probe, a year in which we exceeded performance expectations across our business, while also building a solid foundation for future growth.

In our first full year as an independent public company following our spin-off from Chugai Pharmaceutical Co., Ltd., we achieved record revenues and earnings. For the year, total revenues increased 33%, from $155.6 in 2002 to $207.2 million, driven by strong growth in product sales. And on the bottom line, we grew net income from $13.0 to $35.3 million, an increase of 167% per fully diluted share.

Based on this robust financial performance and our future prospects, our share price more than tripled in 2003, from $11.90 to $36.47 on a split-adjusted basis. We significantly outperformed our peers, with the 206% increase in our stock price outpacing the 46% increase of the NASDAQ biotech index.

Both of our key businesses, clinical diagnostics and blood screening, performed strongly in 2003. Clinical diagnostics growth was driven by rapid adoption of our APTIMA Combo 2 assay, an amplified nucleic acid test we launched in 2001 to simultaneously detect chlamydial infections and gonorrhea. Blood screening growth was driven by sales of the Procleix HIV-1/HCV assay system. We developed and manufacture the Procleix assay, which is marketed by Chiron. The Procleix assay is currently used to test more than 80% of donated blood in the United States, and is gaining share rapidly in international markets.

In addition to our operational and financial successes, we achieved several development and regulatory milestones in 2003 that will drive future growth.

Most importantly, we received FDA approval to test for certain sexually transmitted diseases on our TIGRIS instrument, the first integrated, fully automated, high-throughput testing platform for the molecular diagnostics industry. The TIGRIS instrument, which was approved to run our APTIMA Combo 2 assay, is the first diagnostic instrument to fully automate nucleic acid testing from start to finish. We expect this revolutionary system to significantly reduce labor costs, minimize testing errors, improve operator ergonomics and increase laboratory productivity, thereby increasing our market share in testing for chlamydial infections and gonorrhea. In addition, we are focused on expanding the menu of clinical diagnostic and blood screening tests that can be performed on the TIGRIS platform, so more customers can realize its many benefits.

We accomplished a second major clinical diagnostics milestone in 2003 when we acquired from DiagnoCure exclusive worldwide rights to a new, highly specific prostate cancer marker called PCA3.

We are developing a urine test for PCA3 that may offer significant advantages over traditional Prostate Specific Antigen testing alone, which is imprecise and results in many unnecessary and expensive biopsies. Our collaboration with DiagnoCure accelerates our growth into oncology, and may result in another medically important, high-volume test for our TIGRIS instrument.

Turning to blood screening, I am particularly proud of our ability to respond quickly to the public health threat posed by West Nile virus (WNV) in donated blood. In the fall of 2002, the National Institutes of Health approached us with an urgent request for a WNV test. In a remarkable display of Gen-Probe's technological prowess, we were able to develop an assay in about seven months, in time for testing to begin under an Investigational New Drug Application before the 2003 peak mosquito season.

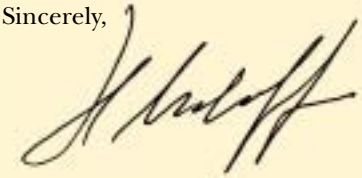
We achieved a second major milestone in our blood screening business in 2003 by beginning U.S. clinical trials of our Procleix Ultrio assay, which adds a test for hepatitis B virus (HBV) to the previously approved assay for HIV-1 and hepatitis C virus. We are conducting the clinical trials on both our semi-automated and TIGRIS instrument platforms. We received a European "CE Mark" for the Procleix Ultrio assay early in 2004, clearing the way for Chiron to launch it in Europe. Adding an HBV test to the currently approved Procleix assay should make us significantly more competitive internationally, where we have less than a 25% share of the blood screening market and therefore a significant growth opportunity.

Our 2003 accomplishments have us well-positioned for strong top- and bottom-line growth in 2004 and beyond. We are excited about our future, and believe we are gaining momentum as a newly independent company. In 2004, we expect growth to be driven by the roll-out of our TIGRIS system in clinical diagnostics, by continued strength in our APTIMA Combo 2 business, by a full year of cost-recovery revenues from our WNV test, and by ongoing international expansion in our blood screening business.

We also expect to achieve several development and regulatory milestones in 2004 that will fuel longer-term growth. For example, we plan to submit a U.S. marketing application for our Procleix Ultrio assay, and also look forward to Chiron's international launch of the assay on the TIGRIS system late this year.

As I think about Gen-Probe's future, I have tremendous confidence in our employees' ability to continue the outstanding innovation and execution that have made us so successful to date. Gen-Probe people continue to impress me with their ability to make the extraordinary seem routine. I thank them for their dedication and achievement, and I thank our loyal shareholders for your ongoing interest and support.

Sincerely,



HENRY L. NORDHOFF
CHAIRMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER

MARCH 29, 2004

☑ **TODAY: FDA APPROVAL**

☐ **TOMORROW: INCREASED APTIMA COMBO 2 MARKET SHARE**

Delivering absolute automation to customers.

TIGRIS SYSTEM

Gen-Probe's TIGRIS instrument is the first integrated, fully automated, high-throughput molecular diagnostic testing platform. The revolutionary platform is expected to help clinical laboratory customers deal with serious shortages of skilled technicians, who also are expensive to hire. The system is designed to improve workflow, reduce labor costs, minimize testing errors, improve operator ergonomics and increase laboratory productivity. It has the ability to process approximately 500 samples in an eight-hour shift and up to 1,000 samples in approximately 13 hours, making it significantly more productive and far more automated than anything currently available.

Late in 2003, Gen-Probe received U.S. marketing clearance from the Food and Drug Administration to run the company's APTIMA Combo 2 assay on the TIGRIS instrument. Gen-Probe expects the TIGRIS platform to accelerate market share growth of the assay, which simultaneously detects chlamydial infections and gonorrhea. Gen-Probe's goal is to add other clinical diagnostic tests to the TIGRIS menu as soon as possible.

The TIGRIS system also may revolutionize the blood screening industry with its extraordinary throughput and ease of use. Early in 2004, Gen-Probe began clinical trials on the TIGRIS system of the Procleix Ultrio assay, which simultaneously detects HIV-1, hepatitis C virus and hepatitis B virus in donated blood. Gen-Probe expects to file a Biologics License Application for the Procleix Ultrio assay on the TIGRIS system in 2004.

Bob Scalese and Valerie Day of Gen-Probe R&D were two leaders of the team that developed the TIGRIS system, which requires no hands-on sample preparation, processing or results analysis.


TIGRIS


GEN-PROBE
RANDY

☑ **TODAY: IN-LICENSED PROSTATE CANCER MARKER**

☐ **TOMORROW: PCA3 TEST ON THE TIGRIS SYSTEM**

APTIMA Combo 2, cancer testing lead growth opportunities.

CLINICAL DIAGNOSTICS

Gen-Probe's clinical diagnostic products test for microorganisms that cause certain sexually transmitted diseases (STDs), tuberculosis, strep throat, pneumonia and certain fungal diseases. The company's products are nucleic acid tests that detect the presence of minute amounts of a microorganism's genetic code. Compared to traditional methods, nucleic acid testing (NAT) offers better performance, shorter testing times and more accurate results.

Gen-Probe's primary growth driver in clinical diagnostics is the APTIMA Combo 2 assay, which simultaneously detects the most common bacterial STDs, chlamydial infections and gonorrhea. APTIMA Combo 2 is an "amplified" test that uses a patented Gen-Probe technology to make the microorganisms easier to detect. Sales of APTIMA Combo 2 grew strongly in 2003, and with FDA approval to run the test on the TIGRIS system, Gen-Probe looks forward to increasing market share further in 2004. Gen-Probe also markets a non-amplified test to detect the same organisms called PACE® 2C, which continues to enjoy significant market share.

In a strategic move to enter the cancer diagnostics market in 2003, Gen-Probe licensed from Canadian-based DiagnoCure Inc. the worldwide rights to a new prostate cancer marker called PCA3. Gen-Probe is developing an innovative urine test to detect this highly specific prostate cancer marker. Because initial studies have shown PCA3 is over-expressed only in malignant prostate tissue, we believe the test may offer advantages over prostate specific antigen (PSA) testing, the current standard for prostate cancer evaluation. The test also may potentially help reduce many of the unnecessary and expensive biopsies that result from the limitations of PSA tests.

Caroline Knott, marketing, and Randy Johnson, PhD, R&D, discuss promotional strategy for the APTIMA Combo 2 assay.

☑ **TODAY: DEVELOPED WNV TEST**

☐ **TOMORROW: COMMERCIAL REVENUES**

Growth from international expansion, new assays.

BLOOD SCREENING

Gen-Probe delivered on its commitment to help improve the safety of the world's blood supply in 2003. Gen-Probe's blood screening assays, which are marketed under the Procleix brand by Chiron, are used to screen for HIV-1, hepatitis C virus (HCV), hepatitis B virus (HBV) and the West Nile virus (WNV).

Gen-Probe's main growth driver in its blood screening business is the Procleix HIV-1/HCV assay, which is used to screen more than 80% of donated blood in the United States. In addition, the assay is approved around the world, and international sales are growing strongly.

In 2003, Gen-Probe began U.S. clinical trials of the Procleix Ultrio assay, which adds another layer of safety to the blood supply by simultaneously detecting HBV, in addition to HIV and HCV. These trials are being conducted on both the semi-automated and TIGRIS systems. HBV, which causes the most common, serious liver infection in the world, can lead to liver failure, cirrhosis or cancer. The Procleix Ultrio assay received European regulatory approval early in 2004, and Chiron is launching it in the European Economic Area, the world's largest blood screening market, and in other countries.

One of Gen-Probe's major accomplishments in 2003 was developing a nucleic acid test to screen donated blood for WNV. The test was developed within months of receiving an urgent request from the National Institutes of Health, and the first shipments occurred in June. Through year-end, more than 6 million U.S. blood donations had been tested for WNV using Gen-Probe's investigational assay, and nearly 900 infected donations had been detected. Gen-Probe receives "cost recovery" revenue for the WNV test, since it has not yet received U.S. regulatory approval. Gen-Probe's goal is to file a Biologics License Application for the assay by the end of the first quarter of 2005.

Jeff Linnen, PhD, and Leslie Stringfellow, PhD, of R&D led the project team that developed Gen-Probe's WNV blood screening assay in record time.


GEN-PROBE
JEFF L.
GEN-PROBE
LESLIE

From Innovative Technologies...

Nucleic Acid Testing

Nucleic acids store and transfer genetic information in cells. The main types of nucleic acids are DNA and RNA, which are made up of chains of chemicals called nucleotides. Most DNA exists in cells as a double-stranded structure that resembles a twisted ladder. The nucleotides on opposite sides of the ladder will attach, or hybridize, to each other only in a precise way. As a result, once scientists have identified a unique genetic sequence within a microorganism (the "target sequence"), they can design a nucleotide probe that will bind specifically to that sequence. The probe, a sequence of nucleotides in a specific order, detects and identifies the target microorganism by binding to its unique, complementary DNA or RNA sequence. DNA probes are the foundation of nucleic acid testing (NAT).

Targeting Ribosomal RNA

Gen-Probe has patented a technique to detect and identify microorganisms using their ribosomal RNA (rRNA) as the target sequence. Each cell contains up to 10,000 copies of rRNA, compared to only one or a few copies of DNA, which competing NAT assays target. The sensitivity of our tests is greatly enhanced because there is much more rRNA to detect than DNA.

Target Capture

To detect small numbers of microorganisms in a large sample, the organisms must be concentrated to a detectable level. Gen-Probe has developed a technique to "capture" targets by immobilizing them on magnetic beads. This technique also enables scientists to wash away materials in the sample that might interfere with accurate results. Our patented target capture technology works with a wide range of samples (urine, blood, etc.), and eliminates the need for customers to use other, more labor-intensive purification steps before performing NAT assays.

...To Superior Key Products

APTIMA Combo 2, which received FDA marketing clearance in August 2001, is an amplified NAT test that simultaneously detects *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in female endocervical and vaginal swab specimens, male urethral swab specimens, and male and female urine specimens. The assay may be used to test symptomatic and asymptomatic people. APTIMA Combo 2 incorporates Gen-Probe's rRNA, target capture, TMA and DKA technologies.

Transcription-Mediated Amplification

The goal of amplification is to reproduce target nucleic acids, which are present in small numbers, so they can be detected using DNA probes. Gen-Probe's patented transcription-mediated amplification (TMA) technology uses two natural enzymes to produce more than 10 billion copies of a target in less than an hour. TMA is less cumbersome and labor intensive than competing technologies, amplifies both DNA and RNA, and minimizes the potential for laboratory contamination and incorrect results.

Chemiluminescent Detection with HPA or DKA

Gen-Probe's DNA probes are labeled with chemicals called acridinium esters (AEs), which generate light when a target microorganism has been detected. Our AE technology is simpler and more sensitive than detection technologies used in most competing assays. AEs are used with our Hybridization Protection Assay (HPA), which eliminates the need for steps used by our competitors that can lead to contamination and false positive results. Finally, Gen-Probe's dual kinetic assay (DKA) uses two types of AEs – one that flashes and another that glows – to detect two different microorganisms simultaneously.

PACE 2C, which received FDA marketing clearance in October 1994, is a non-amplified NAT test that simultaneously detects *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in female endocervical and male urethral swab specimens. Because PACE incorporates Gen-Probe's patented rRNA technology, it is the only non-amplified NAT test to detect the most common bacterial sexually transmitted diseases.

The **Procleix HIV-1/HCV** assay, which received FDA approval in February of 2002, is an amplified NAT test that simultaneously detects HIV-1 and hepatitis C virus in donated blood, plasma, organs and tissue. Gen-Probe developed and manufactures the assay, which is marketed by Chiron. The Procleix assay incorporates Gen-Probe's target capture, TMA and DKA technologies.

GEN-PROBE INCORPORATED

Financial Information

TABLE OF CONTENTS

Selected Financial Data

The selected financial data set forth below with respect to our statements of operations for the years ended December 31, 2003, 2002, and 2001 and, with respect to our balance sheets, at December 31, 2003 and 2002 are derived from our consolidated financial statements that have been audited by Ernst & Young LLP, independent auditors, which are included elsewhere in this report. The statement of operations data for the years ended December 31, 2000 and 1999 and the balance sheet data as of December 31, 2001, 2000, and 1999 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.

(IN THOUSANDS, EXCEPT PER SHARE DATA)

Years Ended December 31	2003	2002	2001	2000	1999
STATEMENT OF OPERATIONS DATA:					
Revenues:					
Product sales	$ 188,645	$ 139,932	$ 104,233	$ 100,162	$ 95,569
Collaborative research revenue	15,402	11,032	20,203	13,764	11,366
Royalty and license revenue	3,144	4,633	5,295	5,615	10,587
Total revenues	207,191	155,597	129,731	119,541	117,522
Operating expenses:					
Cost of product sales	45,458	53,411	38,954	34,463	30,837
Research and development	63,193	46,709	53,967	58,954	48,454
Marketing and sales	22,586	18,199	16,247	14,508	13,088
General and administrative	23,233	20,995	15,564	12,628	11,845
Amortization of intangible assets	372	336	948	948	2,921
Total operating expenses	154,842	139,650	125,680	121,501	107,145
Income (loss) from operations	52,349	15,947	4,051	(1,960)	10,377
Other income (expense):					
Minority interest	(97)	–	–	–	–
Interest income	2,415	906	482	1,029	540
Interest expense	(65)	(1,868)	(1,012)	(1,112)	(1,092)
Other income (expense), net	494	3,238	6	(50)	54
Total other income (expense)	2,747	2,276	(524)	(133)	(498)
Income (loss) before income taxes	55,096	18,223	3,527	(2,093)	9,879
Income tax expense (benefit)	19,766	5,216	(1,090)	(1,085)	3,168
Net income (loss)	$ 35,330	$ 13,007	$ 4,617	$ (1,008)	$ 6,711
Net income (loss) per share[1]:					
Basic	$ 0.74	$ 0.27	$ 0.10	$ (0.02)	$ 0.14
Diluted	$ 0.72	$ 0.27	$ 0.10	$ (0.02)	$ 0.14
Weighted average shares outstanding[1]:					
Basic	47,974	47,600	47,600	47,600	47,600
Diluted	49,137	47,610	47,606	47,600	47,600
BALANCE SHEET DATA:					
Cash, cash equivalents and short-term investments	$ 156,306	$ 107,960	$ 17,750	$ 12,584	$ 24,151
Working capital	169,000	115,288	29,765	29,439	30,523
Total assets	324,741	258,157	160,347	156,612	159,683
Long-term debt, including current portion	-	-	12,000	14,000	14,000
Stockholders' equity	270,375	215,578	115,807	111,180	112,074

[1] All share and per share amounts reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003, the .366153-for-1 reverse stock split effective in 2002 and the 650,000-for-1 stock split effective in August 2000.

Management's Discussion and Analysis of Financial Condition and Results of Operations

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 21 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 immediately after our former parent company, Chugai Pharmaceutical Co., Ltd. distributed all of its shares of our common stock to its shareholders. Since our spin-off into an independent, 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. 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.

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 the 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. For the year ended December 31, 2003, product sales, collaborative research revenues and royalty and license revenues equaled 91%, 7% and 2%, respectively, of our total revenues of $207.2 million.

PRODUCT SALES

Historically, our primary source of revenue has been the sale of clinical diagnostic products in the United States. Our primary clinical diagnostic products include our PACE 2, AccuProbe, Amplified Mycobacterium Tuberculosis Direct Test, and APTIMA Combo 2 product lines. We currently manufacture and ship approximately 22 million tests per year 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. Sales of our PACE family of assays accounted for approximately 29% of our total revenues in 2003 and 44% of our total revenues in 2002.

In 1999, we began to supply NAT assays for use in screening blood donations intended for transfusion. Our first 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 trademark. We recognize product sales from the manufacture and shipment of tests for screening donated blood 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 upon payment by Chiron 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 paid. Net sales are ultimately equal to the sales of the assays by Chiron to third-parties, less freight, duty and certain other adjustments specified in our agreement with Chiron, multiplied by our share of the net revenue, which was 43.0% with respect to sales of assays that include a test for HCV beginning the second quarter of 2002 after 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, such as the Procleix HIV-1/HCV assay and the Procleix Ultrio (HIV-1/HCV/HBV) assay, which received its Community European, or CE, mark in January 2004, 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 West Nile virus, or 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.

In February 2002, the Food and Drug Administration, or FDA, approved our Biologics License Application, or BLA, for our assay used to screen donated blood for HIV-1 and HCV. Accordingly, we began to recognize product sales revenue for tests shipped in the United States in the second quarter of 2002. Outside the United States, the Procleix HIV-1/HCV assay has received CE marking and approval in a number of other countries.

Product sales also include the sales or rental revenue associated with the delivery of our proprietary integrated instrument platforms to customers for performing our NAT assays. We provide multiple instrument rental options to our customers depending on the types and volumes of products purchased. Instruments are manufactured by third-party contractors, but we generally provide technical support and instrument service to maintain these systems in the field. Chiron is responsible for placement and servicing of instruments used in connection with our blood screening business and Bayer and other international distributors are primarily responsible for placement and servicing of instruments used in our clinical diagnostics business outside the United States. Direct sales of our instrument platforms to customers accounted for approximately 3% of our product sales for both the years ended December 31, 2003 and 2002. However, we generally retain title to the instruments and recover our instrument costs in connection with the sale of the assays. The costs associated with the instruments are charged to cost of products sold 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.

COLLABORATIVE RESEARCH REVENUE

We have developed a NAT assay to detect HIV-1 and HCV in donated human blood and have also developed a semi-automated instrument system to conduct the test. These assays and instruments are marketed through our collaboration with Chiron under the Procleix name. The Procleix HIV-1/HCV assays and instrumentation were used in clinical trials, under an IND from early 1999 through 2002. In February 2002, the FDA approved the Procleix HIV-1/HCV assays. FDA approval of the Procleix HIV-1/HCV assays has allowed Chiron to implement commercial pricing for sales of the Procleix HIV-1/HCV assays to United States customers, which resulted in a significant increase in the revenues we received from such sales in the third and fourth quarters of 2002 and all of 2003.

In March 2003, we signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. For the year ended December 31, 2003, we recognized $4.2 million in reimbursements for expenses incurred related to the development of this assay. We have also developed a NAT assay to detect WNV,

which is currently being used in clinical trials under an IND application. We expect to receive further reimbursement for certain costs incurred during the development of the Procleix Ultrio and WNV assays from Chiron and separately from the National Heart, Lung, and Blood Institute, a part of the NIH.

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 approval in foreign countries. We began deliveries of the commercially approved Procleix HIV-1/HCV products to the United States customers in the second quarter of 2002. Accordingly, we began to classify revenues associated with these products as product sales in our financial statements beginning in that period. Collaborative research revenue for the use of our Procleix HIV-1/HCV blood screening products for the year ended December 31, 2002 was $7.1 million. All sales of this assay in 2003 have been classified as product sales. In addition, for the year ended December 31, 2003, we recognized $6.0 million in collaborative research revenue through our collaboration with Chiron from deliveries of WNV tests on a "cost recovery" basis. We expect to continue recognizing these sales as collaborative research revenue until such time as FDA approval has been received.

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. We received a $10.0 million up-front license fee from Chiron in connection with the agreement in 1998 and an additional payment of $8.5 million upon achieving an agreed upon contract milestone in 1999. Additional payments of up to $15.8 million are due to us in the future under the agreement if we achieve certain other specified milestones relating to the development of what we believe to be the world's first fully automated, integrated, high throughput NAT instrument system known as the TIGRIS instrument. Our costs to develop and commercialize the blood screening assays and associated instruments have been substantial and have had a significant impact on our operating results and financial position since 1998. We completed beta evaluations of the TIGRIS instrument for clinical diagnostic applications and undertook initial beta trials for blood screening applications in the third quarter of 2002 and completed a clinical trial of the TIGRIS instrument for diagnostic application in June 2003. We received FDA clearance to run our APTIMA Combo 2 assay on the TIGRIS instrument in December 2003 and, in January 2004, commenced clinical trials of our Procleix Ultrio assay on the TIGRIS instrument for a blood screening application.

In February 2001, we commenced an arbitration proceeding against Chiron in connection with our blood screening collaboration. During the fourth quarter of 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. During the first quarter of 2002, we recognized $2.4 million of the settlement in other income primarily for services provided in prior periods. Additionally, $3.9 million of the settlement was a prepayment for inventory, all of which was recorded into revenues during the first nine months of 2002. The remaining $0.6 million primarily represents the collection of an outstanding receivable. The arbitration proceedings did not result in any disruption in service to our blood screening customers. We are confident that any future disputes that arise between the companies will be resolved equitably through the dispute resolution procedures contained in the collaboration agreement.

In 1996, we were awarded a $7.7 million contract by the National Heart, Lung and Blood Institute, a part of the NIH, to develop NAT assays for screening donor blood for HIV-1 and HCV. In 1998, the contract was modified with the addition of $0.6 million for the development of a semi-automated system for the detection of HIV-1/HCV in

pooled plasma and $4.3 million for the development of HIV-2 and hepatitis B virus, or HBV, tests. 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. The NIH reimbursed us $7.8 million of this cost, and we and Chiron will share equally the remaining costs to complete the project. All payments due to us under these reimbursement contracts have been received and were recorded as collaborative research revenues as reimbursable costs were incurred.

We received a $1.0 million contract extension from the NIH in October 2002 to develop a NAT assay for the detection of the WNV. The NIH allocated an additional $2.47 million to the contract extension in February 2003. Billings under these contract extensions were completed in September 2003. In addition, in February 2003, our initial IND application for the WNV assay was accepted by the FDA. Testing on archived blood samples for WNV began in April 2003. We commenced WNV testing on current donated samples in June 2003. We initiated the development of this assay and have recognized collaborative research revenue under the contract extension as reimbursable costs were incurred. In November 2003, we received an additional $4.3 million contract extension from the NIH for the development of the WNV assay.

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 agreed to develop, manufacture and market NAT assays for viral targets and cancer markers in the clinical diagnostic market with Bayer. We record product sales of the assays to Bayer for use in clinical diagnostic applications at agreed upon transfer prices upon shipment to Bayer.

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 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 the costs applicable to the blood screening development collaboration with Chiron and therefore are not able to quantify the direct costs associated with the collaborative research revenue.

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 Gen-Probe 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. Gen-Probe’s arbitration demand also seeks money damages due to Bayer’s failure to use commercially reasonable efforts to promote, market and sell viral diagnostic assays developed by Gen-Probe. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument and certain assays, and other claims. The matter has been set for hearing beginning on September 13, 2004. There can be no assurances as to the final outcome of the arbitration.

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 achievement of the milestone only if there are no remaining substantive performance obligations under such agreement and the amounts are non-refundable.

In May 1997, we entered into a worldwide collaboration with bioMérieux, Vitek, Inc. The collaboration involved research and development activities, as well as the transfer to bioMérieux, pursuant to separate distribution agreements with bioMérieux S.A., of product distribution rights in international markets, excluding Japan. As part of these agreements, we licensed our NAT technologies to bioMérieux to jointly develop NAT assays and adapt and develop instrumentation during a five-year and ten-year term. In return, bioMérieux paid us $6.0 million of license and prepaid royalty fees in 1997 and an additional $6.0 million of license fees in 1998.

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 covers semi-automated probe assays and advanced, fully-automated probe assays for the diagnosis of infectious diseases and detection of food pathogens. Under the terms of the amended agreements, bioMérieux will pay us royalties based on sales of products incorporating the licensed technologies, subject to a minimum annual royalty payment, which began in January 2002 with respect to the semi-automated probe assays and are scheduled to begin in 2006 with respect to the fully automated probe assays. We will also receive a reduction in the royalties based on the amount of cumulative royalties that have been paid to us. In addition, we transferred to bioMérieux all information, trade secrets, procedures, methods, data and processes necessary for bioMérieux to assume development of the products that are the subject of the agreement in exchange for the prepaid royalties paid under the original agreement. Accordingly, we recognized $0.3 million and $0.8 million in royalty fees related to this agreement in 2001 and 2002, respectively. In addition, we recognized $0.5 million and $0.8 million in minimum annual royalties in 2002 and 2003, respectively, in connection with this license agreement. We amortized previously received license fees in an amount equal to $1.9 million annually through the period ended December 31, 2002.

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, etc., 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 the blood screening development process for the Procleix HIV-1/HCV assays for the United States market, we also manufactured and delivered equivalent products for sale in international markets where governmental approvals had been obtained. However, due to the relatively low initial sales volumes for these products in markets outside of the United States, we continued to charge the costs of manufacturing blood screening products to research and development expense, except for an amount equal to the product sales revenues recorded for international commercial sales, which was charged to cost of product sales and approximates the costs applicable to those product sales. Beginning in 2002, the sales volume for the approved products shipped equaled or exceeded the estimated cost applicable to those product sales, and we ceased the allocation of the costs of manufacturing blood screening products to research and development expense. As a result of the implementation of commercial pricing for our Procleix HIV-1/HCV blood screening assays in the United States, we have classified these costs as costs of product sales rather than research and development expenses. During 2003, our manufacturing facilities produced three WNV development lots and four

Procleix Ultrio development lots. Additionally, several smaller scale WNV and Procleix Ultrio development lots were produced in our pilot manufacturing facility located at Genetic Center Drive. The costs associated with these development lots were classified as research and development expense.

During 2003 and 2002, our blood screening manufacturing facility operated below its potential capacity and will continue to operate below its potential capacity for the foreseeable future. This available capacity, as well as available capacity at our clinical diagnostics manufacturing facility, provides us with the opportunity to expand the manufacturing of both our own products and the products of other companies on a contract basis, without adding substantial fixed manufacturing costs. During 2003, a portion of this available capacity was utilized for development activities, as new product offerings are being identified for commercialization. The costs associated with this excess capacity are included as a component of inventory and cost of product sales except to the extent that available capacity was utilized in the production of pre-commercial development lots. Certain operating costs of our blood screening facility, together with other manufacturing costs for the production of assays that are delivered under the terms of an IND application are classified as research and development expense prior to FDA approval.

RESEARCH AND DEVELOPMENT

In recent years, we have invested significantly in research and development as part of our ongoing efforts to accelerate the development of new products and technologies, particularly our TIGRIS instrument and our Procleix Ultrio assay for screening donated blood. Our research and development expenses consist of expenses associated with 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. Research and development costs in total are expected to increase in the future due to new product development, clinical trial costs and clinical manufacturing costs; however, we expect our research and development expenses as a percentage of total revenues to decline in future periods. 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 research and development 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.

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. 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

REVENUE RECOGNITION

We recognize revenue from product sales when the product is shipped and title and risk of loss has passed and when collection of the resulting receivable is reasonably assured. We record revenue from product sales on our blood screening products shipped to countries where regulatory approval has been received based on a contracted transfer price with our third-party collaboration partner, Chiron. Blood screening product sales are then adjusted monthly upon payment by Chiron 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 paid.

We record 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. We do this because price restrictions apply to these products prior to FDA approval in the United States and in certain foreign countries. As commercial pricing was implemented in the United States, we classified domestic sales of these products as product sales in our financial statements. Chiron began to implement commercial pricing in the United States for the blood screening products in the second quarter of 2002. Commercially approved products that we began shipping in the second quarter of 2002 have been recorded as product sales based on the contracted transfer price with Chiron. Based on the terms of our agreement with Chiron, our ultimate share of the net revenue from sales to the end user will not be known until reported by Chiron to us. Blood screening product sales are adjusted upon payment by Chiron to us of amounts reflecting our ultimate share of net revenue from sales by Chiron of these products, less the transfer price revenues initially paid.

Product sales also include the sales or rental value associated with the delivery of our proprietary integrated instrument platforms performing our NAT assays. 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. The costs associated with an instrument are charged to costs of goods sold on a straight-line basis over the estimated life of an instrument, which ranges from three to five years. The costs to maintain these systems in the field are charged to operations as incurred.

We also recognize collaborative research revenue over the term of various collaboration agreements as negotiated monthly contractual payments are earned or we incur reimbursable costs related to the applicable agreement and when collection of the resulting receivable is reasonably assured. 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 related to a particular milestone are recognized as revenue upon the achievement of specified milestones when (1) we have earned the milestone payment, (2) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, and (3) the fees are non-refundable. Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue in 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 licensee.

COLLECTIBILITY OF ACCOUNTS RECEIVABLE

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

VALUATION OF INVENTORIES

We record valuation adjustments to our inventory balances for estimated excess and obsolete inventory equal to the difference between the cost of such inventory and 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 the other governing bodies commercially approves them. Accordingly, the manufacturing costs of these items in inventory are charged to research and development. 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 realize 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 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

PATENT COSTS

We capitalize the costs incurred to file and prosecute patent applications. We amortize these costs over the lesser of the remaining useful life of the related technology or eight years. At December 31, 2003, capitalized patent costs, which have been included in "Other assets" on the face of the balance sheet, totaled approximately $1.7 million, net of accumulated amortization. We expense all costs related to abandoned patent applications. Historically, our expense related to abandoned patent costs has not been material but, if we elect to abandon any of our currently issued or unissued patents, the related expense could be material to our operations in the period of abandonment.

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 will be amortized over the estimated life of the related product beginning when the product is available for sale. At December 31, 2003, capitalized software development costs related to our TIGRIS instrument totaled $24.9 million. We completed beta evaluations of this instrument for clinical diagnostic applications and undertook initial beta trials for blood screening applications in the third quarter of 2002 and we completed a clinical trial for a diagnostic application in June 2003. We initiated clinical trials of our Procleix Ultrio assay on the TIGRIS instrument for a blood screening application in January 2004. If we are not able to successfully deliver this instrument to the marketplace and attain customer acceptance, the asset could be impaired and an adjustment to the carrying value of this asset would be considered by management at that time. We plan to begin to amortize the capitalized software costs in 2004 on a straight-line basis over 120 months during the second half of 2004.

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, 2003, we had net deferred tax assets of $4.1 million that are more likely than not to be realized. Other than a $2.8 million deferred tax asset and an offsetting $2.8 million tax valuation for assets acquired in the 2002 reorganization, no additional valuation is deemed necessary. In connection with the merger of Gen-Probe Holding Company into us, we recorded approximately $2.8 million 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 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 are being carried forward and may be realized in future periods depending on, among other factors, whether we have 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. Net deferred tax assets of $4.1 million relate to research and investment credits taken in our tax returns, timing differences arising from the recording of deferred revenue and certain reserves and accruals. These amounts are offset by capitalized costs expensed for tax purposes and other items. 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.

RESULTS OF OPERATIONS

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

Years Ended December 31	2003	2002	2001
Total revenues	100%	100%	100%
Product sales	91%	90%	80%
Collaborative research revenue	7%	7%	16%
Royalty and license revenue	2%	3%	4%
Operating expenses:			
Cost of product sales	22%	34%	30%
Research and development	31%	30%	42%
Marketing and sales	11%	12%	13%
General and administrative	11%	13%	11%
Amortization of intangible assets	0%	1%	1%
Total operating expenses	75%	90%	97%
Income from operations	25%	10%	3%
Total other income (expense)	2%	2%	0%
Income before income taxes	27%	12%	3%
Income tax expense (benefit)	10%	4%	(1)%
Net income	17%	8%	4%

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.

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, particularly with our STD products.

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 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

Collaborative research revenue tends to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative research revenues, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate additional collaborative research revenues depends, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners. These relationships may not be established or maintained and current collaborative research revenue may decline.

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.

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 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. 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 obsolete 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 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. Effective January 1, 2004, we will have a decrease in our revenue sharing percentage with Chiron, from 47.5% to 45.75%. This change, combined with lower planned levels of development lots and higher instrument costs, including the amortization of our capitalized software development costs, and related service costs, attributed to the commercial launch of our TIGRIS instrument, should result in lower future gross margin percentage levels compared to 2003. In addition, currently our non-military customers 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 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 research and development 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. Research and development 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 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 general and administrative 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. General and administrative expenses increased $2.2 million 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 the acquisition of the majority ownership of Molecular Light Technology Limited, partially offset by a $1.1 million decrease in professional fees primarily attributed to last year's spin-off from Chugai Pharmaceutical.

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 the prior year. 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 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 (benefit) The expense for income taxes amounted to $19.8 million in 2003, compared to $5.2 million in 2002. The tax expense increase in 2003 was attributable to the pre-tax profit of $55.1 million for 2003, compared to $18.2 million in the prior year. The 2003 tax expense includes the benefit of Federal and state research and investment credits which reduced the combined Federal and state statutory tax rate of approximately 41% to the effective tax rate of 36% in 2003.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

YEAR ENDED DECEMBER 31, 2002 COMPARED TO YEAR ENDED DECEMBER 31, 2001

(Percentages have been rounded to the nearest whole percentage)

Product sales Product sales increased $35.7 million, or 34%, to $139.9 million in 2002 from $104.2 million in 2001. The increase was primarily a result of a $33.1 million increase in commercial sales of Procleix blood screening products, both in the United States and international markets. Procleix blood screening product sales represented $38.0 million or 27% of product sales for the year ended December 31, 2002, compared to $4.9 million, or 5%, of product sales for the year ended December 31, 2001.

In February 2002, the FDA approved our Procleix HIV-1/HCV assay for screening donated human blood. Chiron began implementing commercial pricing for the sale of these products in the United States in the second quarter of 2002. Revenues from the sale of these products are now classified as product sales in our financial statements. We record 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 revenues.

Collaborative research revenue Collaborative research revenue decreased $9.2 million, or 45%, to $11.0 million in 2002 from $20.2 million in 2001. The decrease in 2002 was primarily the result of a $7.4 million decrease in firm support commitment payments recorded in 2002 in connection with tests provided to United States customers through our collaboration with Chiron for pooled blood sampling under the terms of the IND application. In addition, revenues from the NIH organ donor program decreased $1.1 million, to $3.1 million in 2002, from $4.2 million in 2001, reflecting the completion of this contract award in 2002.

Royalty and license revenue Royalty and license revenue decreased $0.7 million, or 13%, to $4.6 million in 2002 from $5.3 million in 2001. The decrease in 2002 was primarily the result of the receipt in the third quarter of 2001 of $2.0 million in license and royalty fees from Chugai Diagnostics Science Co., Ltd. for the licensing of rights to certain patented property and royalties, partially offset by $1.0 million in increased royalties from our collaboration with bioMerieux.

Cost of product sales Cost of product sales increased $14.4 million to $53.4 million, or 38% of product sales revenues in 2002 from $39.0 million, or 37% of product sales revenues, in 2001. The increase in cost of sales was primarily attributable to increased sales volume in 2002 and from recording a greater portion of costs associated with the operation of our blood screening manufacturing facility to cost of product sales in 2002 compared to 2001. A substantial portion of the costs associated with our blood screening product manufacturing facility was classified as research and development expenses prior to receiving FDA approval for our Procleix HIV-1/HCV assay in the United States. The amount included in research and development expense in 2001 was $13.2 million, which includes costs associated with our blood screening product manufacturing facility, as well as scrap charges associated with the production of developmental lots for the assay. The amount included in research and development expense in 2002 was $1.6 million. As a result, cost of product sales increased as a percentage of product sales in 2002 compared to 2001. Our gross profit margin on product sales decreased to 62% in 2002 from 63% in 2001. Gross profit in 2002 benefited by approximately $2.1 million, or 1.5% of product sales, through the delivery to customers of blood screening products that had previously been charged to expense during development.

Research and development Research and development expenses decreased $7.3 million to $46.7 million, or 30% of total revenues, in 2002 from $54.0 million, or 42% of total revenues, in 2001. The decrease was primarily the result of an $11.6 million decrease in research and development expenses as a result of our recording all costs associated with the operation of our blood screening facility to cost of sales following FDA approval of our Procleix HIV-1/HCV assay in February 2002, partially offset by a $1.8 million increase in outside instrument development costs and a $2.5 million increase in personnel expenses.

Marketing and sales Marketing and sales expenses increased $2.0 million to $18.2 million, or 12% of total revenues, in 2002 from $16.2 million, or 13% of total revenues, in 2001. The increase in expenses was primarily related to a $0.9 million increase in personnel costs in our marketing and sales force in 2002 to support increases in sales for our clinical diagnostic products, a $0.2 million increase in professional fees and a $0.9 million increase in other marketing and sales expenses.

General and administrative General and administrative expenses increased $5.4 million to $21.0 million, or 13% of total revenues, in 2002 from $15.6 million, or 12% of total revenues, in 2001. The increase in 2002 was the result of a $2.7 million increase in spending for legal and other professional fees primarily related to Gen-Probe's spin-off from Chugai Pharmaceutical, a $1.1 million increase in salaries and benefits resulting from higher staffing levels and a $0.6 million increase in printing and public relations expenses, primarily relating to the registration of our common stock.

Amortization of intangible assets Amortization of intangible assets decreased $0.6 million to $0.3 million in 2002, from $0.9 million in 2001. Annual amortization of $0.6 million was associated with the goodwill applicable to Gen-Probe Holding Company's purchase of Gen-Probe in 1989. The goodwill is no longer amortized following our implementation of SFAS 142.

Total other income (expense) Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing and other items. The net other income of $2.3 million in 2002 is a $2.8 million increase over the net expense of $0.5 million in 2001. The increase in 2002 was due to the receipt in cash and recognition of 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. In addition, we adopted SFAS No. 145 in 2003 and reclassified the $1.25 million 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, net of tax benefit, to interest expense on the statement of income. The tax benefit has been reflected as a component of income tax expense.

Income tax expense (benefit) The expense for income taxes amounted to $5.2 million in 2002, compared to a $1.1 million benefit in 2001. The 2002 tax expense was attributable to the pre-tax profit of $18.2 million in 2002, less the benefits of Federal and state research and investment credits which reduce the combined Federal and state statutory tax rate of approximately 39% to the effective tax rate of 29% in 2002. The tax benefit of $1.1 million in 2001 reflected an increased level of Federal and state tax credits for research and development in 2001 and the effect of the revisions made to increase our 2000 estimate for research and development tax credits.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

LIQUIDITY AND CAPITAL RESOURCES

Historically, we have financed our operations through cash from operations, cash received from collaborative research agreements, royalty and license fees, the private placement of debt and cash from capital contributions. At December 31, 2003, we had $156.3 million of cash and cash equivalents and short-term investments.

For the year ended December 31, 2003, net cash provided by operating activities was $52.6 million, compared to $42.2 million for the year ended December 31, 2002. The increase was primarily the result of net income of $35.3 million plus depreciation and amortization of $15.8 million in 2003, compared to net income of $13.0 million plus depreciation and amortization of $17.8 million in 2002.

Our investing activities used cash of $74.8 million for the year ended December 31, 2003, compared to $80.7 million for the year ended December 31, 2002. During 2003, we paid $4.1 million, net of cash acquired, for the acquisition of a majority interest in Molecular Light Technology Limited. In addition, our investing activities consisted of purchases, net of proceeds of $52.7 million for short-term investments and $12.2 million for capital expenditures. 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. However, the average age of our property, plant and equipment is approximately five years, which gives us flexibility in planning capital expenditures.

Net cash provided by financing activities was $14.9 million for the year ended December 31, 2003, compared to $63.9 million for the year ended December 31, 2002. During 2002, cash provided by investing activities consisted of $75.9 million in cash received from our merger with Gen-Probe Holding Company, Inc., partially offset by $12.0 million in payments made on our long term debt during 2002. During the year ended December 31, 2003, we received $14.9 million from the proceeds of stock option exercises and purchases made through our Employee Stock Purchase Plan, or ESPP. On a going-forward basis, cash from financing activities will be affected by receipts from sales of stock under our ESPP and from the exercise of stock options. 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, 2003, we were in compliance with all covenants.

In 2004, we expect to commence the construction of an additional building at our Genetic Center Drive location. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 160,000 square feet built out with interior improvements. The additional space that will not initially be built out will allow for future expansion. The project is estimated to take two years for completion and is currently estimated to cost approximately $35.0 to $40.0 million. These costs will be capitalized as incurred and deprecation will commence upon our completion and use, which is planned for early 2006.

We plan to implement a new Enterprise Resource Planning, or ERP, software system effective in 2005, which is currently estimated to represent an approximate $6.0 to $7.0 million expenditure; the majority of these costs are expected to be incurred during 2004.

Further, we expect to incur approximately $10.0 million to purchase TIGRIS instruments that will be added to our installed base during 2004.

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, 2003 were as follows (amounts in thousands):

Contractual Obligations	Total	2004	2005	2006	2007	2008
Operating leases[1]	$ 6,416	$ 2,116	$ 1,849	$ 1,590	$ 765	$ 96
Material purchase commitment[2]	8,800	8,800	–	–	–	–
Total[3]	$ 15,216	$ 10,916	$ 1,849	$ 1,590	$ 765	$ 96

(1) Reflects obligations on facilities under operating leases in place as of December 31, 2003. 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.

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, we agreed to pay the costs related to the clinical trial for the next joint development project with Chiron. Our obligation is limited to the cost incurred for the previous joint clinical trial, which was approximately $4.1 million. As of December 31, 2003, we had incurred approximately $1.0 million of clinical trial expenses and we anticipate these costs will continue through the end of 2005.

Our primary short-term needs for capital, which are subject to change, are for 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 anticipate additional funds from these sources as reimbursable costs are incurred, but these funds may not materialize and these relationships may not continue.

We believe that our available cash balances, anticipated cash flows from operations 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations (continued)

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In September 2002, we repaid the remaining principal on the fixed rate financing of our headquarters building. 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 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.

We are exposed to foreign exchange risk for expenditures in certain foreign countries, but the total receivables and payables denominated in foreign currencies at December 31, 2003 were not material. We believe that our business operations are not exposed to market risk relating to commodity price risk.

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, 2003.

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.

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.

Report of Ernst & Young LLP, Independent Auditors

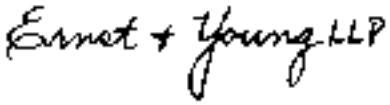
THE BOARD OF DIRECTORS AND STOCKHOLDERS
GEN-PROBE INCORPORATED

We have audited the accompanying consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2003 and 2002, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the 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, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Notes 1 and 4 to the consolidated financial statements, effective January 1, 2002, the Company adopted Financial Accounting Standards Board No. 142, "Goodwill and Other Intangible Assets."



San Diego, California
January 30, 2004

GEN-PROBE INCORPORATED

Consolidated Balance Sheets

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

December 31	2003	2002
Current assets:		
Cash and cash equivalents	$ 35,973	$ 43,118
Short-term investments	120,333	64,842
Trade accounts receivable, net of allowance for doubtful accounts of $717 and $787 at December 31, 2003 and 2002, respectively	15,158	11,891
Accounts receivable - other	2,555	1,024
Inventories	15,096	12,928
Deferred income taxes	10,979	7,178
Prepaid expenses and other current assets	8,783	5,114
Total current assets	208,877	146,095
Property, plant and equipment, net	65,478	65,870
Capitalized software	24,872	22,802
Goodwill	18,621	18,621
Other assets	6,893	4,769
Total assets	$ 324,741	$ 258,157
Current liabilities:		
Accounts payable	9,250	8,148
Accrued salaries and employee benefits	11,670	8,961
Other accrued expenses	6,085	5,704
Income tax payable	6,191	894
Deferred revenue	6,681	7,100
Total current liabilities	39,877	30,807
Deferred income taxes	6,850	5,112
Deferred revenue	5,667	6,333
Deferred rent	323	327
Minority interest	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; 100,000,000 shares authorized, 48,721,560 and 47,599,890 shares issued and outstanding at December 31, 2003 and 2002, respectively[1]	5	5
Additional paid-in capital	212,586	192,624
Deferred compensation	(538)	–
Accumulated other comprehensive income	343	300
Retained earnings	57,979	22,649
Total stockholders' equity	270,375	215,578
Total liabilities and stockholders' equity	$ 324,741	$ 258,157

[1] All share and per share amounts reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003 and the .366153-for-1 reverse stock split effective in August 2002.

See accompanying notes to consolidated financial statements.

Consolidated Statements of Income

(IN THOUSANDS, EXCEPT PER SHARE DATA)

Years Ended December 31	2003	2002	2001
Revenues:			
Product sales	$ 188,645	$ 139,932	$ 104,233
Collaborative research revenue	15,402	11,032	20,203
Royalty and license revenue	3,144	4,633	5,295
Total revenues	207,191	155,597	129,731
Operating expenses:			
Cost of product sales	45,458	53,411	38,954
Research and development	63,193	46,709	53,967
Marketing and sales	22,586	18,199	16,247
General and administrative	23,233	20,995	15,564
Amortization of intangible assets	372	336	948
Total operating expenses	154,842	139,650	125,680
Income from operations	52,349	15,947	4,051
Other income (expense):			
Minority interest	(97)	–	–
Interest income	2,415	906	482
Interest expense	(65)	(1,868)	(1,012)
Other income (expense), net	494	3,238	6
Total other income (expense)	2,747	2,276	(524)
Income before income taxes	55,096	18,223	3,527
Income tax expense (benefit)	19,766	5,216	(1,090)
Net income	$ 35,330	$ 13,007	$ 4,617
Net income per share[1]:			
Basic	$ 0.74	$ 0.27	$ 0.10
Diluted	$ 0.72	$ 0.27	$ 0.10
Weighted average shares outstanding[1]:			
Basic	47,974	47,600	47,600
Diluted	49,137	47,610	47,606

[1] All share and per share amounts reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003 and the .366153-for-1 reverse stock split effective in August 2002.

See accompanying notes to consolidated financial statements.

GEN-PROBE INCORPORATED

Consolidated Statements of Stockholders' Equity

(IN THOUSANDS)

	Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2000	47,600	$ 5	$ 106,100	$ –	$ 50	$ 5,025	$ 111,180
Comprehensive income:							
Net income	–	–	–	–	–	4,617	4,617
Unrealized gains on short-term investments, net of income tax expense of $2	–	–	–	–	10	–	10
Comprehensive income					4,627		
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 issuance of restricted shares	–	–	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

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows

(IN THOUSANDS)

Years Ended December 31	2003	2002	2001
Operating activities			
Net income	$ 35,330	$ 13,007	$ 4,617
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	15,822	17,784	16,953
Stock compensation charges	149	–	–
Loss on disposal of property and equipment	102	308	115
Deferred rent	(4)	30	297
Stock option income tax benefits	4,387	–	–
Deferred revenue	(1,085)	1,221	(918)
Deferred income taxes	(2,239)	1,106	(892)
Minority interest	37	–	–
Changes in assets and liabilities:			
Accounts receivable	(2,164)	6,219	(372)
Inventories	(2,108)	(1,924)	1,505
Prepaid expenses and other current assets	(3,669)	640	(2,107)
Accounts payable	310	58	1,256
Accrued salaries and employee benefits	2,710	1,920	1,647
Other accrued expenses	(259)	(1,059)	85
Income tax payable	5,297	2,927	47
Net cash provided by operating activities	52,616	42,237	22,233
Investing activities			
Proceeds from sales and maturities of short-term investments	42,722	–	6,353
Purchases of short-term investments	(95,421)	(64,842)	(2,432)
Purchases of property, plant and equipment	(12,238)	(12,616)	(10,749)
Capitalization of license fee	(3,000)	–	–
Cash paid for acquisition of Molecular Light Technology Limited, net of cash acquired	(4,133)	–	–
Capitalization of software development costs	(2,070)	(3,011)	(3,366)
Capitalization of patent costs	(635)	(678)	(900)
Other assets	(12)	400	(30)
Net cash used in investing activities	(74,787)	(80,747)	(11,124)

(Continued on next page.)

Consolidated Statements of Cash Flows (CONTINUED)

(IN THOUSANDS)

Years Ended December 31	2003	2002	2001
Financing activities			
Principal payments on long-term debt	–	(12,000)	(2,000)
Capital contribution from merger with Gen-Probe Holding	–	75,878	–
Proceeds from issuance of common stock	14,888	–	–
Net cash provided by (used in) financing activities	14,888	63,878	(2,000)
Effect of exchange rate changes on cash	138	–	–
Net increase (decrease) in cash and cash equivalents	(7,145)	25,368	9,109
Cash and cash equivalents at the beginning of year	43,118	17,750	8,641
Cash and cash equivalents at the end of year	$ 35,973	$ 43,118	$ 17,750
Supplemental disclosure of cash flow information:			
Cash paid (received) for:			
Interest	$ 63	$ 754	$ 998
Income taxes	$ 11,913	$ 2,104	$ (745)
Non-cash financing activities:			
Contribution of non-cash items from merger with Gen-Probe Holding	$ –	$ 10,646	$ –

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

Note 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION

Gen-Probe Incorporated ("Gen-Probe" or the "Company") is engaged in developing, manufacturing and marketing of 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.

On August 7, 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, giving the Company a total ownership of 82.6% when added to the 17% 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 that of the Company as of the date of acquisition. MLT is a biotechnology company from which Gen-Probe licenses chemiluminescent technology it uses in its Hybridization Protection Assay ("HPA"). 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 wholly-owned subsidiaries, Gen-Probe Sales and Services, Inc., Gen-Probe Canada, Inc., Gen-Probe UK Limited and Molecular Light Technology Limited and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

REPORTING PERIODS

The Company operates and reports on fiscal periods ending on the Friday closest to the end of the month except for year-end, which closes 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, 2003, 2002 and 2001 each included 52 weeks.

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

Assets and liabilities recorded in foreign currencies are translated at the exchange rate on the balance sheet date. Revenue and expenses are translated at average rates of exchange prevailing during the year. Translation adjustments resulting from this process are charged or credited to other income (expense).

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

Notes to Consolidated Financial Statements

(continued)

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.

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 measures compensation expense for its employee stock-based compensation using the intrinsic value method and provides pro forma disclosures of net income and earnings per common share as if the fair value methods had been applied in measuring compensation expense. 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.

Pro forma information regarding net income is required to be disclosed in interim financial statements by SFAS No. 148, and has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method of SFAS No. 123. The fair value for these options was estimated at the dates 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 pricing model for all option grants made subsequent to that date. The following weighted average assumptions were used:

Years Ended December 31	2003	2002	2001
Risk free interest rate	2.76%	3.82%	4.33%
Dividend yield	0%	0%	0%
Volatility factor	47%	72%*	0%
Expected life (in years)	4	4	4
Resulting average fair value	$ 10.78	$ 0.91	$ 1.81

* Amount represents the average volatility for options granted from September 16, 2002 - December 31, 2002

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	2003	2002	2001
Net income:			
As reported	$ 35,330	$ 13,007	$ 4,617
Stock-based employee compensation expense included in reported net income, net of related tax effects	37	–	–
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(3,092)	(792)	(1,940)
Pro forma net income	$ 32,275	$ 12,215	$ 2,677
Net income per share:			
As reported			
Basic	$ 0.74	$ 0.27	$ 0.10
Diluted	$ 0.72	$ 0.27	$ 0.10
Pro forma			
Basic	$ 0.67	$ 0.26	$ 0.06
Diluted	$ 0.66	$ 0.26	$ 0.06

The pro forma effects on net income for the years ended December 31, 2003, 2002 and 2001 are not likely to be representative of the effects on reported net income in future years. In management's opinion, existing stock option valuation models do not provide a reliable single measure of the fair value of employee stock options that have vesting provisions and are not transferable. In addition, 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.

REVENUE RECOGNITION

Revenue is recognized from sales of our clinical diagnostic products when the product is shipped and title and risk of loss has passed and when collection of the resulting receivable is reasonably assured. The Company records revenue from product sales on its blood screening products shipped to countries where regulatory approval has been received based on a contracted transfer price with its third-party collaboration partner. Blood screening product sales are then adjusted monthly upon payment by the Company's collaboration partner to the Company of amounts reflecting the Company's ultimate share of net revenue from sales by the collaboration partner to the end user less the transfer price revenues previously paid.

The Company records revenues related to use of its 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 apply to those products prior to FDA license approval in the United States and similar approval in foreign countries.

Product sales also include the sales or rental revenue associated with the delivery of the Company's proprietary instrument platforms for performing its diagnostic tests. Historically, the Company has provided its instrumentation to 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 recently has begun to implement multi-year sales contracts that have an equipment factor set forth in them. The costs associated with the instrument are charged to costs of goods sold 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 operations as incurred.

In addition to collaborative research revenue previously recorded in connection with sales of blood screening products in the United States and other countries in which products have not received regulatory approval, 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

Notes to Consolidated Financial Statements

(continued)

to the agreement. Milestone payments are recognized as revenue upon (i) the achievement of specified milestones when the Company has earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone was 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 in 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 licensee.

COST OF REVENUES

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

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 the 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 $2,258,000, $1,780,000 and $2,096,000 for the years ended December 31, 2003, 2002 and 2001, 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.

CAPITALIZED SOFTWARE COSTS

The Company capitalizes costs incurred in the development of computer software after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and will be amortized over the estimated life of 10 years beginning when the TIGRIS instrument is available for sale.

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 $14,380,000, $15,632,000 and $14,457,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Amortization of leasehold improvements is provided over the shorter of the remaining life of the lease or estimated useful life of the asset. Patents and trademarks are stated at cost and amortized on a straight-line basis over the lesser of the remaining useful life of the related technology or the estimated useful life of 8 years. 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 fiscal 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 2003 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. With the adoption of SFAS No. 142, the Company no longer amortizes goodwill, which reduced annual amortization expense and increased the Company's operating income by $612,000.

The following table presents a reconciliation of net income and per share data to what would have been reported had the new rules been in effect during the year ended December 31, 2001 (in thousands, except per share data):

Year Ended December 31,	2001
Reported net income	$ 4,617
Add back goodwill amortization, net of tax	612
Adjusted net income	$ 5,229
Basic and diluted net income per common share:	
Reported net income	$ 0.10
Goodwill amortization, net of tax	0.01
Adjusted net income	$ 0.11

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, 2003.

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 consists of unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income.

RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred.

INCOME TAXES

The Company was included along with its former sister company, Chugai Pharma USA, LLC ("CPUSA"), in the consolidated federal and in various combined state income tax returns of Gen-Probe Holding. 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 the 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.

RECLASSIFICATIONS

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

RECENT ACCOUNTING PRONOUNCEMENTS

In November 2002, the FASB issued Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 clarifies the requirements of SFAS No. 5, "Accounting for Contingencies," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 are effective for annual periods ending after December 15, 2002. However, the provisions for initial recognition and

Notes to Consolidated Financial Statements

(continued)

measurement are effective on a prospective basis for guarantees issued or modified after December 31, 2002. The adoption of FIN 45 did not have an impact on the Company's consolidated financial statements.

In January 2003, the FASB issued Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities." This Interpretation requires that if a business enterprise has a controlling financial interest in a variable interest entity, the assets, liabilities, and results of activities of the variable interest entity should be included in the consolidated financial statements of the business enterprise. FIN 46 is effective for variable interest entities created after January 31, 2003. FIN 46 is an interpretation of Accounting Research Bulletin No. 51, "Consolidated Financial Statements." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. The adoption of this interpretation did not have an impact on our financial condition or results of operations.

In April 2003, the FASB issued SFAS No. 149 ("SFAS 149"), "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under Statement 133. SFAS 149 requires that contracts with comparable characteristics be accounted for similarly. In particular, SFAS 149 (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative, (2) clarifies when a derivative contains a financing component, and (3) amends the definition of underlying to conform it to language used in FIN 45. SFAS 149 is effective for contracts entered into or modified after June 30, 2003. We do not expect this interpretation to have a significant impact on our financial condition or results of operations.

In May 2003, the FASB issued SFAS No. 150 ("SFAS 150"), "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS 150 establishes standards for how to classify and measure certain financial instruments with characteristics of both liabilities and equity. It is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of this interpretation did not have an impact on our financial condition or results of operations.

NET INCOME PER SHARE

Gen-Probe 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 had 48,721,560 shares of stock outstanding as of December 31, 2003 and 47,559,890 shares of common stock outstanding as of December 31, 2002. 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	2003	2002	2001
Net income	$ 35,330	$ 13,007	$ 4,617
Weighted average shares outstanding - Basic	47,974	47,600	47,600
Effect of dilutive common stock options outstanding	1,163	10	6
Weighted average shares outstanding - Diluted	49,137	47,610	47,606
Net income per share:			
Basic	$ 0.74	$ 0.27	$ 0.10
Diluted	$ 0.72	$ 0.27	$ 0.10

Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 588,292, 3,929,148 and 2,561,692 for the years ended December 31, 2003, 2002 and 2001, respectively were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Note 2. BALANCE SHEET INFORMATION

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

INVENTORIES

December 31	2003	2002
Raw materials and supplies	$ 5,874	$ 4,504
Work in process	3,118	1,295
Finished goods	6,104	7,129
	$ 15,096	$ 12,928

PROPERTY, PLANT AND EQUIPMENT

December 31	2003	2002
Land	$ 9,100	$ 9,100
Building	40,534	38,203
Machinery and equipment	88,416	79,529
Leasehold improvements	17,551	17,283
Furniture and fixtures	9,473	8,793
Property, plant and equipment (at cost)	165,074	152,908
Less accumulated depreciation and amortization	(99,596)	(87,038)
Property, plant and equipment (net)	$ 65,478	$ 65,870

OTHER ASSETS

December 31	2003	2002
Patents and other intangible assets	$ 14,866	$ 14,230
Purchased intangible assets	36,636	33,636
Other	260	330
	51,762	48,196
Less accumulated amortization	(44,869)	(43,427)
	$ 6,893	$ 4,769

OTHER ACCRUED EXPENSES

December 31	2003	2002
Royalties	$ 2,315	$ 2,161
Patent and legal	690	829
Sales tax payable	459	236
Professional fees	400	1,471
Other	2,221	1,007
Total	$ 6,085	$ 5,704

As of December 31, 2003, the Company has capitalized $24,872,000 in software costs associated with the development of the TIGRIS instrument. In addition, the Company has in aggregate $10,703,000 in TIGRIS related items consisting of inventories, machinery and equipment and prepaid expenses.

Note 3. SHORT-TERM INVESTMENTS

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

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2003, by contractual maturity, are as follows (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Maturities				
Within one year	$ 36,287	$ 148	$ (1)	$ 36,434
After one year through five years	83,694	217	(12)	83,899
Total short-term investments	$ 119,981	$ 365	$ (13)	$ 120,333

The following is a summary of short-term investments as of December 31, 2002 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate obligations	$ 14,799	$ 114	$ (1)	$ 14,912
Mortgage backed government securities	29,300	109	–	29,409
Municipal securities	20,428	93	–	20,521
Total short-term investments	$ 64,527	$ 316	$ (1)	$ 64,842

Gross realized gains and losses on sales of short-term investments were not significant in 2003, 2002 or 2001.

Notes to Consolidated Financial Statements

(continued)

Note 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								
	2003			2002			2001		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:									
Capitalized software	$ 24,872	$ –	$ 24,872	$ 22,802	$ –	$ 22,802	$ 19,791	$ –	$ 19,791
Patents	14,764	13,073	1,691	14,128	12,003	2,125	13,437	10,187	3,250
Deferred financing costs	72	72	–	72	72	–	72	34	38
Organizational costs	30	30	–	30	30	–	30	26	4
Goodwill	–	–	–	–	–	–	24,901	7,677	17,224
Purchased intangibles	36,636	31,694	4,942	33,636	31,322	2,314	33,636	30,986	2,650
Total	$ 76,374	$ 44,869	$ 31,505	$ 70,668	$ 43,427	$ 27,241	$ 91,867	$ 48,910	$ 42,957
Intangible assets not subject to amortization:									
Goodwill	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621	$ –	$ –	$ –

The Company had aggregate amortization expense of $1,442,000, $2,194,000 and $2,261,000 in 2003, 2002 and 2001, respectively. The expected future annual amortization expense of the Company's intangible assets is as follows (in thousands):

Years Ended December 31	Amortization Expense
2004	$ 2,590
2005	3,551
2006	3,170
2007	3,147
2008	3,059
Thereafter	15,987
Total	$ 31,504

Note 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 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, 2003, 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 before interest, taxes, depreciation and amortization. The Company was in compliance with all covenants at December 31, 2003.

Note 6. RELATED PARTY TRANSACTIONS

The Company had royalty expense of $1,451,000, $2,467,000 and $2,368,000 in 2003, 2002 and 2001, respectively, to MLT 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 consolidation.

Gen-Probe's product sales to Chugai and its former subsidiary, Chugai Diagnostics Science Co., Ltd. ("CDS"), totaled $2,730,000 and $3,040,000 during 2002 and 2001, respectively. Trade and other accounts receivable from Chugai or its subsidiaries other than the Company were $306,000 and $245,000 at December 31, 2002 and 2001, respectively. In June 2002, Gen-Probe reimbursed CDS $146,000 for certain import license fees from Japanese regulatory authorities that CDS had paid on our behalf.

In 1997, the Company completed the construction of its headquarters facility on land which was purchased by Gen-Probe Holding in 1995. Gen-Probe Holding reimbursed Gen-Probe $2,997,000 for costs related to land improvements under the terms of an agreement between Chugai Pharma U.S.A., Inc. and Gen-Probe. In 1997, Gen-Probe and Gen-Probe Holding entered into a long-term ground lease agreement whereby Gen-Probe leased the land under the operating facility from Gen-Probe Holding at a rate of $525,000 per year. Under the ground lease agreement, Gen-Probe paid Gen-Probe Holding $0, $306,000 and $525,000 for the years ended December 31, 2003, 2002 and 2001. Effective with the reorganization on July 31, 2002, this land was titled to Gen-Probe and the ground lease was terminated.

Note 7. INCOME TAXES

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

Years Ended December 31	2003	2002	2001
Current:			
Federal	$ 20,316	$ 3,788	$ (230)
International	500	127	–
State	1,264	238	12
	22,080	4,153	(218)
Deferred:			
Federal	(3,443)	1,524	1,551
International	219	–	–
State	910	(461)	(2,423)
	(2,314)	1,063	(872)
	$ 19,766	$ 5,216	$ (1,090)

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 $1,000,000 at December 31, 2003, 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.

Notes to Consolidated Financial Statements

(continued)

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

December 31	2003	2002
Deferred tax assets:		
Research and California manufacturers' investment credit carryforwards	$ 4,457	$ 5,546
Inventory reserves and capitalization	8,333	4,621
Allowance for doubtful accounts	302	348
Deferred revenue	2,498	2,711
Depreciation	376	120
Other accruals and reserves (net)	1,932	1,946
Total deferred tax assets	17,898	15,292
Valuation allowance	(2,847)	(2,847)
Total net deferred tax assets	15,051	12,445
Deferred tax liabilities:		
Purchased intangibles	(769)	(897)
Capitalized costs expensed for tax purposes	(10,153)	(9,482)
Total net deferred tax liabilities	(10,922)	(10,379)
Net deferred tax assets	$ 4,129	$ 2,066

In connection with the merger of Gen-Probe Holding into Gen-Probe, Gen-Probe 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 Chugai Pharma USA, LLC, the successor to Gen-Probe'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, Gen-Probe'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.

Other than the valuation allowance for the net deferred tax assets from CPUSA, 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, 2003, the Company had alternative minimum tax ("AMT") credit carryforwards of approximately $381,000.

At December 31, 2003, the Company also had California research and development credit carryforwards of approximately $5,947,000. 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.

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	2003	2002	2001
Taxes at federal statutory rate	$ 19,305	$ 6,378	$ 1,203
State taxes, net of federal benefit	2,356	723	121
Federal tax credit	(1,500)	(1,000)	(1,300)
State tax credits	(943)	(943)	(865)
Other	548	58	(249)
	$ 19,766	$ 5,216	$ (1,090)
Taxes at federal statutory rate	35%	35%	35%
State taxes, net of federal benefit	5%	4%	4%
Federal tax credit	(3)%	(5)%	(38)%
State tax credits	(2)%	(5)%	(25)%
Other	1%	-%	(7)%
	36%	29%	(31)%

Note 8. STOCKHOLDERS' EQUITY

On September 5, 2003, the Company's Board of Directors authorized a two-for-one stock split implemented as a 100% stock dividend, effective September 30, 2003 for holders of record as of September 16, 2003 (the "Stock Split"). In August 2002, the Company's Board of Directors authorized a .366153-for-1 reverse stock split. All share information has been retroactively restated to reflect the Stock Split and the reverse stock split.

On December 10, 2001, Chugai announced its intention to spin-off Gen-Probe by distributing all of its shares of Gen-Probe to the shareholders of Chugai, subject to Chugai shareholder approval and Chugai's merger with Nippon Roche Kabushiki Kaisha, a subsidiary of Roche Pharmaholding B.V., and a capital reduction transaction involving the distribution of the Gen-Probe shares. On June 27, 2002, Chugai's shareholders approved the merger and the

capital reduction transaction and on September 15, 2002, Chugai completed the distribution by distributing all of its 23,799,945 shares of Gen-Probe to the shareholders of Chugai. The common shares distributed were listed on the Nasdaq National Market and began trading on September 16, 2002. Prior to the spin-off, Chugai commenced a reorganization that resulted in Gen-Probe becoming a wholly owned subsidiary of Chugai. As part of the reorganization, on July 23, 2002, Gen-Probe Holding merged into Gen-Probe, making Gen-Probe a wholly owned subsidiary of Chugai. Gen-Probe Holding was a non-operating holding company that at the time of the merger had approximately $75,900,000 in cash and owned 37 acres of land, including the site of Gen-Probe's headquarters.

The merger of Gen-Probe Holding into Gen-Probe 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 of Gen-Probe Holding acquired are 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.

In connection with the merger of Gen-Probe Holding into Gen-Probe, Gen-Probe 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 Chugai Pharma USA, LLC, the successor to Gen-Probe'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, Gen-Probe's having sufficient taxable income in the future periods. The deferred tax assets recorded were fully offset by a valuation reserve until these deductions and credits are realized.

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 August 2003, the Company granted 20,000 shares of restricted stock to its chief executive officer under the 2003 Incentive Award Plan of Gen-Probe Incorporated (the "2003 Plan"), resulting in deferred compensation of $600,000 associated with this grant. The deferred compensation is being amortized to expense over the vesting period of the restricted stock.

During 2003, the Company issued 3,718 shares of common stock to members of the Board of Directors as partial consideration for services rendered. The Company recognized expense for these grants totaling $87,000, 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, as adjusted to reflect the Stock Split. 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, as adjusted to reflect the Stock Split. 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, as adjusted to reflect the Stock Split. 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 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, 2000		2,632,668	$ 13.66
Granted	1,310,606	12.83	
Exercised	–	–	
Cancelled	(339,158)	13.63	
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

The following table summarizes information about stock options outstanding at December 31, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Shares Exercisable	Weighted Average Exercise Price
$ 6.75 – $ 12.03	327,437	8.9	$ 9.70	71,474	$ 8.17
$ 12.29	1,340,128	8.1	12.29	413,995	12.29
$ 13.50 – $ 15.51	1,998,531	7.0	13.69	1,461,182	13.66
$ 19.19 – $ 27.50	281,398	9.6	22.91	–	–
$ 29.53	1,298,200	9.6	29.53	–	–
$ 30.68 – $ 34.72	226,826	9.7	32.05	–	–
	5,472,520	8.3	$ 18.10	1,946,651	$ 13.16

Options available for future grant are 3,648,470 at December 31, 2003.

Notes to Consolidated Financial Statements

(continued)

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

Years Ended December 31	2003	2002	2001
Exercise price equal to the fair value of common stock on the grant date:			
Weighted-average exercise price	$ 27.19	$ 8.68	$ 12.69
Weighted-average option fair value	$ 10.78	$ 4.41	$ 2.02
Exercise price greater than deemed fair value of common stock on the grant date:			
Weighted-average exercise price	$ –	$ 12.66	$ 13.66
Weighted-average option fair value	$ –	$ 0.17	$ 0.81

EMPLOYEE STOCK PURCHASE PLAN

In May 2003, the Company adopted the Employee Stock Purchase Plan ("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 will be 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 2003, employees purchased 34,714 shares at an average price of $16.91. As of December 31, 2003, 965,286 shares were reserved for future issuances under the ESPP.

Note 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, 2003 are as follows (in thousands):

2004	$ 2,116
2005	1,849
2006	1,590
2007	765
2008	96
Total payments	$ 6,416

Rent expense was $1,700,000, $1,727,000 and $1,116,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

COLLABORATIVE AGREEMENTS

Effective May 2, 1997, the Company entered into agreements which created a worldwide relationship between Gen-Probe and bioMérieux Vitek, Inc. ("bMx"). The collaboration involved research and development activities, as well as the transfer to bMx of product distribution rights in international markets, excluding Japan. As part of the agreements, Gen-Probe 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 return, bMx paid Gen-Probe $2,000,000 of license and $4,000,000 of prepaid royalty fees in 1997 and an additional $6,000,000 of license fees in 1998. License fees were amortized over the term of the agreement and royalty fees were deferred.

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 $0, $1,250,000 and $250,000 for the years ended December 31, 2003, 2002, and 2001, respectively. Gen-Probe recognized $1,870,000 in license fees related to this agreement for each of the years ended December 31, 2002 and 2001. In 2003, Gen-Probe recognized $750,000 in minimum annual royalties.

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. The Company received an additional payment of $8,500,000 in 1999 upon achieving a milestone under the agreement which the Company recorded as revenue. The Company may receive additional payments if certain milestones are met. The Company may also receive additional revenues if products are sold. 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, 2003, 2002 and 2001, respectively, related to this aspect of the agreement.

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 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. Collaborative research revenue recorded under the terms of the agreements for the years ended December 31, 2002 and 2001 were $7,100,000 and $14,546,000, respectively. 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 year ended December 31, 2003, the Company recognized $6,000,000 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, or 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 year ended December 31, 2003, the Company received $4,200,000 in reimbursements for certain costs incurred during 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.

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 is limited to the cost incurred for the previous joint clinical trial, which was approximately $4,100,000. For the year ended December 31, 2003, the Company incurred approximately $1,000,000 in clinical trial expenses and anticipates that these costs will continue through the end of 2005.

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.

Notes to Consolidated Financial Statements

(continued)

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 $569,000, $494,000 and $421,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

In July 2001, the Company granted a license to CDS, now Rebio Gen, Inc., for certain patented products. In exchange for this license, Gen-Probe received an initial license fee of $1,600,000 and will receive a royalty on all sales of licensed products under the agreement. Royalties of $257,000, $290,000 and $400,000 were received by the Company in 2003, 2002 and 2001, respectively, on sales of products sold by CDS.

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 years ended December 31, 2002 and 2001 were $3,067,000 and $4,222,000, respectively. 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 supports the Company's pursuit of clinical studies and submission of a Biologics License Application ("BLA"), for our nucleic acid test for the detection of WNV in donated human blood. The Company has initiated the development of this assay and will recognize collaborative research revenue under the contract extension as reimbursable costs are incurred. Contract revenues recorded for the year ended December 31, 2003 were $1,350,000.

LITIGATION

The Company is a party to the following litigation and is currently participating 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 its former affiliates, as well as Becton Dickinson and bioMérieux have willfully infringed United States patent no. 4,900,659, or the " '659 patent," through the manufacture and sale of products for the diagnosis of gonorrhea. On January 24, 2001, the District Court granted the Company's motion for summary judgment, finding that the '659 patent is invalid. Enzo appealed the judgment to the Federal Circuit Court of Appeals. On July 15, 2002, a panel of the Federal Circuit Court, after having previously affirmed the District Court's summary judgment decision, granted Enzo's petition for rehearing and, without hearing further argument, reversed the District Court's order granting summary judgment and remanded the case to the District Court for further proceedings. Following remand from the Court of Appeals, the Company's former affiliates and bioMérieux were dismissed from the case by Enzo. The Company and Becton Dickinson remain as defendants. The Company anticipates that trial in the case may be set for the fourth quarter of 2004. The Company expects Enzo to assert a damage claim based on a contention that Enzo is 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. 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.

Vysis, Inc. In December 1999, the Company initiated litigation in the United States District Court for the Southern District of California against Vysis, now a subsidiary of Abbott Laboratories, seeking a declaratory judgment that the Company's products were not covered by a Vysis patent that is the subject of a license granted by Vysis in favor of the Company and that the patent is invalid and unenforceable. In August 2002, following a jury trial, the District Court entered judgment in the Company's favor, finding the Vysis patent invalid and finding that the patent does not cover Gen-Probe's products. On September 3, 2002, Vysis filed a notice of appeal with the District Court. Further, on October 22, 2002 while Vysis' appeal was pending, the United States Patent & Trademark Office reissued the Vysis patent with amended claims. On October 22, 2002, the Company filed a second lawsuit in District Court to challenge the validity and scope of the reissued patent. On March 5, 2004, the Court of Appeals vacated the District Court's August 2002 judgement in favor of the Company and directed the District Court to dismiss the case on the ground of lack of subject matter jurisdiction. The Company intends to petition the Court of Appeals for rehearing and rehearing en banc. There can be no assurances as to the final outcome of this litigation. The Company has at all times maintained the license with Vysis in full force and continued to make royalty payments under the license, pending final resolution of the litigation.

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 states that Bayer has 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. Gen-Probe's arbitration demand also seeks money damages due to Bayer's failure to use commercially reasonable efforts to promote, market and sell viral diagnostic assays developed by Gen-Probe. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS system, alleged delays in the development of certain assays, and other claims. The matter has been set for hearing beginning September 13, 2003. There can be no assurances as to the final outcome of the arbitration.

OTHER

The Company is obligated to purchase raw materials used in manufacturing and instrumentation from two key vendors. The minimum purchase commitment is approximately $8,800,000 for the year ended December 31, 2004.

Note 10. SIGNIFICANT CUSTOMERS AND GEOGRAPHIC INFORMATION

During the years ended December 31, 2003, 2002 and 2001, 42%, 30% and 11%, respectively, of net revenues were from one customer. During the year ended December 31, 2001, 17% of net revenues were from a second customer. No other customer accounted for more than 10% of revenues in any fiscal year.

During the years ended December 31, 2003, 2002 and 2001, 41%, 27% and 5%, 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, 2003, 2002 and 2001, 59%, 73% and 95%, respectively, of product sales were from the sale of clinical diagnostic products and instruments.

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

Years Ended December 31	2003	2002	2001
Net revenue:			
North America	$ 180,924	$ 132,355	$ 111,018
Rest of World	26,267	23,242	18,713
	$ 207,191	$ 155,597	$ 129,731

Notes to Consolidated Financial Statements

(continued)

Note 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 first day of the month following the month in which 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 $1,110,000, $985,000 and $835,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

Note 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, 2003 (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 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
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[1]	$ 0.18	$ 0.17	$ 0.18	$ 0.20
Diluted[1]	$ 0.18	$ 0.17	$ 0.18	$ 0.19
2002				
Total revenues	$ 33,783	$ 34,851	$ 42,797	$ 44,166
Cost of product sales	11,614	12,603	14,723	14,471
Total operating expenses	33,080	34,658	34,745	37,167
Net income	3,084	550	4,423	4,950
Net income per share				
Basic[1]	$ 0.06	$ 0.01	$ 0.09	$ 0.10
Diluted[1]	$ 0.06	$ 0.01	$ 0.09	$ 0.10

[1] Earnings per share have been restated to reflect a two-for-one stock split implemented as a 100% stock dividend in September 2003 and a .366153-for-1 reverse stock split effective in August 2002.

Market for Registrant's Common Equity and Related Stockholder Matters

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.

2002	High	Low
Third Quarter (beginning September 16, 2002)	$ 8.78	$ 6.60
Fourth Quarter	$ 12.46	$ 6.76

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

As of March 1, 2004, there were approximately 11,108 holders 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.

Board of Directors

Henry L. Nordhoff
Chairman, President and Chief Executive Officer
Gen-Probe Incorporated

Raymond V. Dittamore
Former Partner
Ernst & Young LLP

Armin M. Kessler
Former Chief Operating Officer
Hoffmann-La Roche

Mae C. Jemison, MD
Founder, BioSentient Corporation and The Earth We Share™

Gerald D. Laubach, PhD
Former President
Pfizer Inc.

Brian A. McNamee, MBBS
Chief Executive Officer and Managing Director
CSL Ltd.

Phillip M. Schneider
Former Chief Financial Officer
IDEC Pharmaceutical Corp.

The Honorable Abraham D. Sofaer
George P. Shultz Distinguished Scholar and Senior Fellow
The Hoover Institution
Stanford University

Seated from left: Abraham Sofaer, Henry Nordhoff and Armin Kessler. Standing from left: Brian McNamee, Mae Jemison, Gerald Laubach, Phillip Schneider and Raymond Dittamore.

EXECUTIVE MANAGEMENT

Henry L. Nordhoff
Chairman, President and Chief Executive Officer

Niall M. Conway
Executive Vice President Sales and Operations

James H. Godsey, PhD
Executive Vice President Development

Daniel L. Kacian, PhD, MD
Executive Vice President and Chief Scientist

R. William Bowen
Vice President General Counsel and Secretary

Glen Paul Freiberg, RAC
Vice President Regulatory, Quality and Government Affairs

Larry T. Mimms, PhD
Vice President Strategic Planning and Business Development

Herm Rosenman
Vice President Finance and Chief Financial Officer

Robin Vedova
Vice President Administration

SCIENTIFIC ADVISORY BOARD

Doug Richman, MD
Chairman, Gen-Probe Scientific Advisory Board and Professor, University of California, San Diego

Harvey Alter, MD
Chief, Infectious Diseases Section, Department of Transfusion Medicine, Clinical Center, National Institutes of Health

Daniel Farkas, PhD
President of the Association for Molecular Pathology, Associate Professor, Baylor College of Medicine

Herb Fritsche, PhD
Professor of Pathology and Laboratory Medicine, University of Texas M.D. Anderson Cancer Center

Ann Kessler, PhD
Director, Spectrum Pharmaceuticals, and Chairman of Science and Development Advisory Committee, Maxim Pharmaceuticals

Thomas Quinn, MD
Professor of Medicine, Johns Hopkins University

STOCKHOLDER INFORMATION

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www.gen-probe.com

STOCK LISTING
Gen-Probe is listed on The Nasdaq Stock Market under the symbol GPRO

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San Diego, California 92101

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San Diego, California 92121

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Toll-Free Japanese Language: 866-241-9991
Toll-Free from Japan: 00531-11-4916

ANNUAL MEETING
Gen-Probe's annual meeting of stockholders will be held at 10:00 a.m. May 28, 2004, at the company's headquarters facility, 10210 Genetic Center Drive, San Diego, California. Detailed information about the meeting is contained in the Notice of Annual Meeting and Proxy Statement sent to each stockholder of record as of April 15, 2004.

REQUESTS FOR INFORMATION
Gen-Probe invites stockholders, security analysts, representatives of portfolio management firms and other interested parties to contact:

Investor Relations
Gen-Probe Incorporated
10210 Genetic Center Drive
Phone: 858-410-8904
Fax: 858-410-8220
Email: IR@gen-probe.com

A copy of Gen-Probe's annual report on Form 10-K, as filed with the U.S. Securities and Exchange Commission, is available free of charge by contacting us at the address above, and at www.gen-probe.com.

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This annual report includes forward-looking statements related to our business prospects. Any statements in this annual report about our expectations, beliefs, plans, objectives, assumptions or future events or performance, including those in the Chairman's letter to stockholders and under the headings including "2003 Achievements," "2004 Goals," "TIGRIS System/Delivering Absolute Automation to Customers," "Clinical Diagnostics/APTIMA Combo 2, Cancer Testing Lead Growth Opportunities," "Blood Screening/Growth From International Expansion, New Assays," "From Innovative Technologies," and "To Superior Key Products," are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan," and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future organizational structure are all 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 those expressed or implied by any forward-looking statement. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to: (i) the risk that we may not achieve our expected 2004 growth targets, (ii) the possibility that the market for the sale of our new products, such as our APTIMA Combo 2 assay and TIGRIS instrument system, may not develop as expected, (iii) the enhancement of existing products and the development of new products may not proceed as planned, (iv) the risk that our Ultrio Assay and West Nile virus clinical trials may not proceed as planned and may not be successful, (v) the risk that our Ultrio Assay and West Nile virus products may not be commercially available in the time frames we anticipate, or at all, (vi) we may not be able to compete effectively, (vii) we may not be able to maintain our current corporate collaborations and enter into new corporate collaborations, (viii) we are dependent on Chiron Corporation, Bayer Corporation and other third parties for the distribution of some of our products, (ix) we are dependent on a small number of customers, contract manufacturers and single source suppliers of raw materials, (x) changes in third-party reimbursement policies regarding our products could adversely affect sales of our products, (xi) changes in government regulation affecting our diagnostic products could harm our sales and increase our development costs, and (xii) our involvement in patent and other intellectual property litigation could be expensive and could divert management's attention.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements. For additional information about risks and uncertainties we face and a discussion of our financial statements and footnotes, see documents we have filed with the SEC, including our Annual Report on Form 10-K filed with the SEC on March 9, 2004, and all our periodic filings made with the SEC. We assume no obligation and expressly disclaim any duty to update any forward-looking statement to reflect events or circumstances after the date of this annual report or to reflect the occurrence of subsequent or unanticipated events.

Gen-Probe Incorporated

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San Diego, California 92121

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