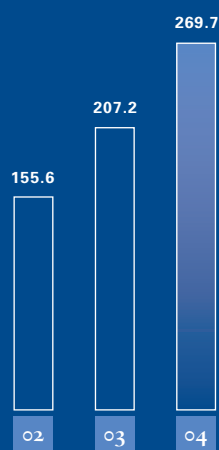




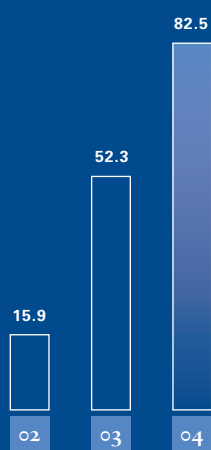
Gen-Probe

2004 ANNUAL REPORT EXECUTING OUR STRATEGY

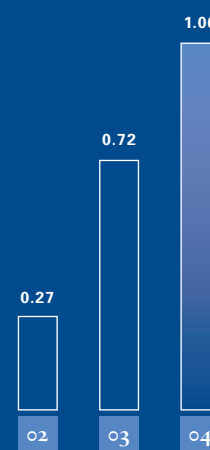
Gen-Probe (NASDAQ: GPRO) is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid testing (NAT) products used to diagnose human diseases and screen donated human blood.



TOTAL REVENUES
In Millions of Dollars



OPERATING INCOME
In Millions of Dollars



EARNINGS PER DILUTED SHARE
In Dollars

Financial Highlights

IN THOUSANDS EXCEPT PER SHARE DATA

FOR THE YEARS ENDED DECEMBER 31,	2002	2003	2004
INCOME STATEMENT			
Total revenues	\$ 155,597	\$ 207,191	\$ 269,707
Product sales	\$ 139,932	\$ 188,645	\$ 222,560
Research and development	\$ 47,045	\$ 63,565	\$ 68,482
Operating income	\$ 15,947	\$ 52,349	\$ 82,498
Net income	\$ 13,007	\$ 35,330	\$ 54,575
Earnings per diluted share	\$ 0.27	\$ 0.72	\$ 1.06
BALANCE SHEET			
Cash and short-term investments	\$ 107,960	\$ 156,306	\$ 193,826
Total assets	\$ 258,157	\$ 324,741	\$ 411,082
Long-term debt, including current portion	\$ 0	\$ 0	\$ 0
Stockholders' equity	\$ 215,578	\$ 270,375	\$ 361,029



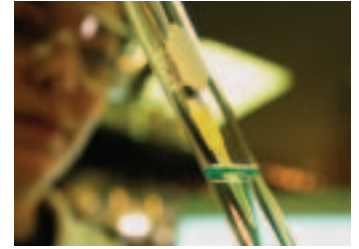
pg 4 | Sexually Transmitted Diseases



pg 6 | Oncology



pg 8 | HIV and Hepatitis C Virus

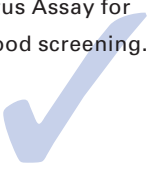
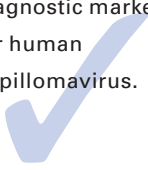


pg 10 | Hepatitis B Virus and West Nile Virus

2004 Achievements

<p>JANUARY 2004 Secured European regulatory approval of the PROCLEIX® ULTRIO™ Assay, which detects HIV-1, hepatitis C virus and hepatitis B virus in donated blood.</p>	<p>JANUARY 2004 Launched the TIGRIS® DTS™ System, the first fully automated, high-throughput nucleic acid testing instrument, with Gen-Probe's APTIMA COMBO 2® Assay.</p>	<p>AUGUST 2004 Placed TIGRIS Systems at U.S. blood centers in areas with high incidence of West Nile virus, enabling testing of individual blood donations.</p>	<p>SEPTEMBER 2004 Submitted Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) to commercialize the Procleix Ultrio Assay for blood screening.</p>	<p>DECEMBER 2004 Secured European regulatory approval to run the Procleix Ultrio Assay on the TIGRIS System.</p>	<p>DECEMBER 2004 / JANUARY 2005 Licensed rights from Corixa to develop molecular diagnostic tests for various cancers, and technology from AdnaGen to increase cancer test accuracy.</p>
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2005 Goals

<p>File a BLA for the Procleix West Nile Virus Assay for blood screening.</p> 	<p>Gain access to the molecular diagnostic market for human papillomavirus.</p> 	<p>Increase market share of the APTIMA Combo 2 Assay by running it on the TIGRIS System.</p>	<p>Through marketing partner Chiron, drive international growth of the Procleix HIV-1/HCV and Procleix Ultrio Assays.</p>	<p>Gain U.S. marketing clearance for the Procleix Ultrio Assay for blood screening.</p>	<p>Achieve strong growth in revenues and earnings per share consistent with financial guidance.</p>
<p><i>Submitted application to FDA in January.</i></p>	<p><i>Signed supply and purchase agreement with Roche in February.</i></p>				



Dear Fellow Shareholders,

Gen-Probe had an excellent year in 2004, a year in which we successfully blended execution in the short term with innovation for the long term. Not only did we post financial results that exceeded expectations, we made excellent progress in ensuring the future growth of our Company.

In our second full year as an independent public company following the spin-off from Chugai, we made key strategic moves toward achieving our mission — becoming the world leader in nucleic acid testing (NAT) for human disease.

Gen-Probe's financial performance established new records in 2004 and reflected excellent execution across our business. On the top line, annual product sales increased to \$222.6 million, an 18% increase compared to 2003. This strong growth in product sales helped drive total revenues up 30%, to \$269.7 million. And on the bottom line, net income increased 54%, to \$54.6 million, while earnings per diluted share surged 47%, to \$1.06.

Based on these results, our share price appreciated by 24% in 2004, outperforming the 9% increase in the NASDAQ Composite Index and the 6% rise in the NASDAQ Biotech Index.

Both our core businesses, clinical diagnostics and blood screening, performed strongly in 2004.

Clinical diagnostics sales, which rose 13% in 2004, benefited from two main factors.

First, sales of APTIMA Combo 2, our amplified assay that simultaneously detects chlamydial infections and gonorrhea, continued to grow strongly. Sales increased by over 50% in 2004, driven by the assay's superior sensitivity and specificity, and by the added value of running the test on our unique TIGRIS System. The system, which we launched in the first quarter of 2004, is the only fully automated, high-throughput instrument in the NAT industry.

Second, even as APTIMA Combo 2 gained market share, sales of our PACE[®] Assay, our older, non-amplified test for the same microorganisms, remained resilient. PACE remains a durable standard among STD tests — a highly accurate, easy-to-use assay for patient populations with a low prevalence of sexually transmitted diseases (STDs).

We also executed well in our blood screening business during 2004, as sales increased 25%. This robust growth came from continued international expansion of the Procleix Assay, our duplex test that simultaneously detects HIV-1 and the hepatitis C virus in donated blood; the European launch of the Procleix Ultrio Assay, which adds a test for hepatitis B to our duplex test; and incremental market share gains in the United States for our Procleix Assay.

From a commercial perspective, 2004 was a very good year in blood screening, but we are even more excited about how innovation has set the stage for longer-term growth in the business.

In recent months we achieved development and regulatory milestones that we believe will pay off this year and in 2006. For example, we completed pivotal clinical trials and filed Biologics License Applications (BLAs) to market both our Procleix Ultrio and West Nile Virus (WNV) Assays in the United States.

Since investigational testing for WNV began in the summer of 2003, our assay has intercepted approximately 1,200

“From a commercial perspective, 2004 was a very good year, but we are even more excited about how innovation has set the stage for longer-term growth in the business.”

infected blood donations. In addition, we revolutionized the blood screening industry in 2004 by providing the TIGRIS Instrument on an investigational basis to blood centers in areas with a high prevalence of WNV. The high-throughput capability of the TIGRIS System enabled these blood centers to screen each unit of blood individually, rather than in pools, thereby maximizing the sensitivity of screening.

Based on products such as the WNV Assay and the TIGRIS Instrument, both our STD and blood screening businesses are poised for future growth. In addition, we have tremendous opportunities to use our innovative technologies to penetrate new markets, such as cancer diagnostics.

We took important strides toward building an oncology business in 2004 and early 2005. First, we made substantial progress in developing a new prostate cancer test based on the PCA3 gene, the most specific prostate cancer marker discovered to date. Second, we licensed from Corixa the rights to develop NAT tests for approximately 50 genetic markers of genitourinary and other cancers. And third, we signed a supply and purchase agreement with Roche that will enable us to enter the molecular diagnostic market for human papillomavirus (HPV), the leading cause of cervical cancer.

As we evaluate the long-term potential of our Company, we believe this oncology strategy, combined with ongoing initiatives in the STD and blood screening markets, have us well positioned for growth through the end of the decade.

In the near term, 2005 is shaping up to be another year of solid product sales growth, driven by continued market share gains for APTIMA Combo 2 on the TIGRIS System, ongoing international expansion of the Procleix Assay, and increasing traction from the launch of the Procleix Ultrio Assay in Europe, especially on the TIGRIS System.

As we pursue these sizable opportunities this year, and as we look ahead to U.S. commercial revenue from our Procleix Ultrio and West Nile Virus Assays next year, I have tremendous confidence in the ability of Gen-Probe employees to continue to blend execution with innovation. This is the formula that has enabled us to deliver outstanding returns to our shareholders, and that will help us maintain our track record in the future. I am grateful to our employees for their talent and dedication, and to our shareholders for your continued support.



Henry L. Nordhoff
Chairman, President and Chief Executive Officer
March 18, 2005

Sexually Transmitted Diseases

Strong sales of APTIMA Combo 2 and PACE Assays help total clinical diagnostics revenues increase to \$127 million in 2004, 13% higher than in the prior year.



APTIMA COMBO 2
PACE
TIGRIS SYSTEM

Gen-Probe's most important clinical diagnostic products are nucleic acid tests (NATs) to detect chlamydial infections and gonorrhea, the two most common bacterial sexually transmitted diseases, or STDs.

In the United States alone, approximately 54 million tests for these diseases were performed in 2004, representing a market of nearly \$220 million. More than half of these tests were performed with Gen-Probe products.

Gen-Probe offers its customers, which include reference laboratories, hospitals and public health centers, multiple options for STD testing. For example, the PACE product line, which was introduced in 1988, was the first approved NAT for detecting chlamydial infections and gonorrhea, and it remains the test of choice for many customers today. Gen-Probe's newer APTIMA Combo 2 Assay, which was launched in 2001, uses a proprietary technology called Transcription-Mediated Amplification to provide even more sensitive detection of the same microorganisms. The APTIMA Combo 2 Assay is approved to run on Gen-Probe's high-throughput TIGRIS System, the first fully automated instrument for nucleic acid diagnostics. Combining this highly accurate assay with the productivity of the TIGRIS System helped sales of the APTIMA Combo 2 Assay increase by more than 50% in 2004.

Gen-Probe strives to develop NATs that meet the needs of diverse customer segments. For example, early in 2004 the U.S. Food and Drug Administration (FDA) cleared the APTIMA Combo 2 Assay to detect chlamydial infections and gonorrhea from self-collected vaginal swabs. The Company also received approvals late in 2004 and early in 2005 for its standalone APTIMA Assays to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. These assays enable customers to test for either organism alone.



Gen-Probe's most important clinical diagnostic products detect the common sexually transmitted diseases chlamydia and gonorrhea. If undiagnosed and therefore untreated, these infections can cause pelvic inflammatory disease, ectopic pregnancy and infertility, among other complications.

Oncology

Gen-Probe begins building oncology business by developing assays to help diagnose prostate and cervical cancer.



PCA3 FOR PROSTATE CANCER
HUMAN PAPILLOMAVIRUS
TIGRIS SYSTEM

Gen-Probe's mission is to broaden its proprietary nucleic acid testing technologies into new markets where there are important unmet medical needs and attractive commercial opportunities. Oncology is one of these markets, based in part on an aging population and advances in cancer treatment.

Gen-Probe entered the oncology field in late 2003 by acquiring the exclusive worldwide diagnostic rights to a gene called PCA3, which is the most specific prostate cancer marker identified to date. PCA3 is profoundly over-expressed only in cancerous prostate tissue. In contrast, the most common prostate cancer marker used today, prostate specific antigen (PSA), can be expressed in roughly equal levels by both healthy and cancerous prostate tissue. As a result, PSA testing produces a large number of "false positive" results, which can lead to unnecessary biopsies. In 2004, Gen-Probe made excellent progress toward developing a PCA3 Assay that is more accurate than PSA testing, and expects to introduce a preliminary version of the product by the end of 2005.

Another growing molecular diagnostics market is human papillomavirus (HPV) testing. Persistent infection with certain high-risk HPV subtypes is acknowledged as the primary cause of cervical cancer. An estimated 10,000 Americans will develop invasive cervical cancer in 2005 and almost 4,000 women will die from it. If detected early, however, cervical cancer is almost always curable, which illustrates the importance of diagnostic testing for the disease. In early 2005, Gen-Probe signed a supply and purchase agreement with Roche under which Gen-Probe will purchase products for use in APTIMA format test kits to detect high-risk subtypes of HPV.

Also in early 2005, Gen-Probe licensed the rights to develop molecular diagnostic tests for approximately 50 potential genetic markers for genitourinary and other cancers. The agreement broadens Gen-Probe's strategic focus on oncology diagnostics, and provides an array of long-term growth opportunities.



Prostate cancer is the second most common cancer among men. More than 230,000 new cases are expected in the United States in 2005, and more than 30,000 men will die from the disease. Gen-Probe's investigational PCA3 Assay may detect prostate cancer more accurately than current tests, thereby reducing unnecessary biopsies or enabling men to be treated earlier and more appropriately.

HIV and Hepatitis C Virus

Strong sales of the Procleix HIV-1/HCV Assay help overall blood screening sales increase to \$96 million in 2004, 25% higher than in the prior year.




PROCLEIX ASSAY
TIGRIS SYSTEM

Gen-Probe's primary blood screening product is the Procleix Assay, a nucleic acid test that blood centers use to simultaneously detect HIV-1 and the hepatitis C virus (HCV) in donated human blood. HIV-1 is the virus that causes AIDS, and HCV infection can lead to liver failure and death. The Procleix Assay received marketing clearance from the U.S. Food and Drug Administration in 2002.

Each year more than 14 million units of blood are donated in the United States and screened with a nucleic acid test (NAT). The Procleix HIV-1/HCV Assay gained market share in the United States during 2004 and is now used to screen well over 80% of donations, thereby preventing virally contaminated blood from being transfused into healthy blood recipients.

The Procleix Assay detects the unique genetic codes of HIV-1 and HCV directly in donated blood. In contrast, immunoassay tests must wait for the body's immune system to respond to the viruses, and then detect the resulting antibodies. By detecting the viruses directly, the Procleix Assay has reduced the risk of contracting HIV-1 or HCV from a blood transfusion.

Although the Procleix Assay has a dominant share of the U.S. blood screening market, the assay has tremendous growth potential internationally. Although countries such as England and Korea have recently begun NAT testing, about a third of the roughly 40 million annual blood donations in the non-U.S. industrialized world are not screened with an approved NAT test. In addition, 20 million units of blood are donated annually in developing countries such as China and India. As nations continue to modernize their healthcare systems, Gen-Probe expects to benefit from increased levels of nucleic acid testing, as well as from continued market share gains.



One in 20 Americans will need a blood transfusion at some point in their lives as a result of a traumatic injury, surgery, or treatment for certain diseases. Based in large part on the ability of our Procleix Assay to detect HIV-1 and the hepatitis C virus directly in donated blood, the risk of contracting one of these infections from a blood transfusion is approximately one in 2 million.

Hepatitis B Virus and West Nile Virus

Gen-Probe sets stage for future growth by submitting U.S. regulatory applications for the Procleix Ultrio and West Nile Virus Assays.



PROCLEIX ULTRIO ASSAY
PROCLEIX WNV ASSAY
TIGRIS SYSTEM


Gen-Probe expects near-term growth in its blood screening business to be driven in part by U.S. commercial approvals of the Procleix Ultrio and West Nile Virus (WNV) Assays.

The Procleix Ultrio Assay is used to screen donated blood for the hepatitis B virus (HBV), in addition to HIV-1 and HCV. Hepatitis B is the most common serious liver infection in the world and is transmitted through infected blood and body fluids. HBV infection can lead to liver failure, cirrhosis or cancer. More than 350 million people worldwide are chronically infected with HBV and more than one million people die annually as a result of HBV infections.

The Procleix Ultrio Assay received European regulatory approval early in 2004 and was cleared to run on the fully automated TIGRIS System in Europe late in 2004. In addition, Gen-Probe submitted a Biologics License Application (BLA) for the assay to the U.S. Food and Drug Administration (FDA) in September of 2004. The Company expects approval in late 2005.

Since July of 2003, U.S. blood centers have used the Procleix WNV Assay to screen more than 19 million units of donated blood under an Investigational New Drug application. This testing has intercepted approximately 1,200 WNV-infected units, thereby preventing transfusion of contaminated blood into as many as 3,600 people.

Following the completion of pivotal clinical trials late in 2004, Gen-Probe submitted a BLA for the WNV assay to the U.S. FDA in early 2005. Gen-Probe is seeking approval to run both the Procleix Ultrio and WNV Assays on the Company's semi-automated instrumentation and on the fully automated, high-throughput TIGRIS System. The TIGRIS System allows blood centers to test individual blood samples with greater operator efficiency. Testing individual blood donations provides for maximum sensitivity, which is especially important for hard-to-detect viruses such as HBV and WNV.

A person is seen from behind, standing in a river and fly fishing. They are wearing a red cap, a light blue long-sleeved shirt, a tan vest, and dark brown pants. The sky is a mix of deep blue and white clouds, with sunlight filtering through. The water is calm, reflecting the sky and the surrounding trees. The overall mood is serene and outdoorsy.

WNV is a mosquito-borne virus that can cause human disease ranging from mild, flu-like symptoms to severe neurological disease and even death. People who spend significant time outdoors, especially during peak mosquito season, are at higher risk of being infected. Gen-Probe's WNV assay has intercepted approximately 1,200 infected blood donations since investigational testing began in mid-2003.

Financial Information

TABLE OF CONTENTS

Selected Financial Data	13
Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Reports of Ernst & Young LLP, Independent Registered Public Accounting Firm	32
Consolidated Balance Sheets	34
Consolidated Statements of Income	35
Consolidated Statements of Cash Flows	36
Consolidated Statements of Stockholders' Equity	38
Notes to Consolidated Financial Statements	39
Market for Registrant's Common Equity and Related Stockholder Matters	59

Selected Financial Data (IN THOUSANDS, EXCEPT PER SHARE DATA)

The selected financial data set forth below with respect to our consolidated statements of income for each of the three years in the period ended December 31, 2004 and, with respect to our consolidated balance sheets, at December 31, 2004 and 2003 are derived from our consolidated financial statements that have been audited by Ernst & Young LLP, independent registered public accounting firm, which are included elsewhere in this report. The statement of income (loss) data for the years ended December 31, 2001 and 2000 and the balance sheet data as of December 31, 2002, 2001, and 2000 are derived from our audited consolidated financial statements that are not included in this report. The selected financial information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this report.

YEARS ENDED DECEMBER 31,	2004	2003	2002	2001	2000
STATEMENT OF INCOME (LOSS) DATA:					
Revenues:					
Product sales	\$ 222,560	\$ 188,645	\$ 139,932	\$ 104,233	\$ 100,162
Collaborative research revenue	27,122	15,402	11,032	20,203	13,764
Royalty and license revenue	20,025	3,144	4,633	5,295	5,615
Total revenues	269,707	207,191	155,597	129,731	119,541
Operating expenses:					
Cost of product sales	59,908	45,458	53,411	38,954	34,463
Research and development	68,482	63,565	47,045	54,915	59,902
Marketing and sales	27,191	22,586	18,199	16,247	14,508
General and administrative	31,628	23,233	20,995	15,564	12,628
Total operating expenses	187,209	154,842	139,650	125,680	\$ 121,501
Income (loss) from operations	82,498	52,349	15,947	4,051	(1,960)
Net income (loss)	\$ 54,575	\$ 35,330	\$ 13,007	\$ 4,617	\$ (1,008)
Net income (loss) per share					
Basic	\$ 1.10	\$ 0.74	\$ 0.27	\$ 0.10	\$ (0.02)
Diluted	\$ 1.06	\$ 0.72	\$ 0.27	\$ 0.10	\$ (0.02)
Weighted average shares outstanding					
Basic	49,429	47,974	47,600	47,600	47,600
Diluted	51,403	49,137	47,610	47,606	47,600
BALANCE SHEET DATA AS OF DECEMBER 31:					
Cash, cash equivalents and short-term investments	\$ 193,826	\$ 156,306	\$ 107,960	\$ 17,750	\$ 12,584
Working capital	234,202	169,000	115,288	29,765	29,439
Total assets	411,082	324,741	258,157	160,347	156,612
Long-term debt, including current portion	—	—	—	12,000	14,000
Stockholders' equity	361,029	270,375	215,578	115,807	111,180

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

This report contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 which provides a "safe harbor" for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. These risks and uncertainties include those listed on the inside back cover of this report. We assume no obligation to update any forward-looking statements. The audited consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto for the years ended December 31, 2004, 2003 and 2002 in the Annual Report on Form 10-K.

OVERVIEW

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for the screening of donated human blood. We have over 22 years of nucleic acid detection research and product development experience, and our products, which are based on our patented nucleic acid testing, or NAT, technology, are used daily in clinical laboratories and blood collection centers in major countries throughout the world.

In September 2002, our common stock began trading on the NASDAQ National Market. As a publicly traded company, we have achieved strong growth in both revenues and earnings due principally to the success of our blood screening products which are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, hepatitis C virus, or HCV, and hepatitis B virus, or HBV. Under our collaboration agreement with Chiron Corporation, or Chiron, we are responsible for the research, development, regulatory process and manufacturing of our blood screening products while Chiron is responsible for marketing, sales, distribution and service of those products.

RECENT EVENTS

Financial Results During 2004, we achieved strong financial results. Net income for the year was \$54.6 million (\$1.06 per diluted share), compared to \$35.3 million (\$0.72 per diluted share) in 2003, an increase of 54%. Total revenues for 2004 were \$269.7 million, compared to \$207.2 million in 2003, an increase of 30%. Product sales for 2004 were \$222.6 million, compared to \$188.6 million in 2003, an increase of 18%. During 2004, net income and total revenues included a contract milestone of \$6.5 million from Chiron and a license fee of \$7.0 million earned in connection with our cross-licensing agreement with Tosoh Corporation, or Tosoh. These amounts added approximately \$0.17 to diluted earnings per share and \$13.5 million to revenues.

Corporate Collaborations In January 2005, bioMérieux and its affiliates exercised an option to develop diagnostic products for certain undisclosed disease targets using our patented ribosomal RNA technologies, pursuant to the terms of a September 2004 agreement. In exchange for these rights, bioMérieux and its affiliates paid us a \$4.5 million license fee. We have recorded \$1.9 million of the cumulative payments (\$4.5 million license fee and \$0.25 million option fee) as license revenue in the first quarter of 2005, based on the

total number of targets that may eventually be selected. The amount and timing of additional revenue that we record will depend on the number of additional targets, if any, selected by bioMérieux, which also has options to develop diagnostic products for other disease targets by paying us up to an additional \$3 million by the end of 2006. Further, we will receive royalties on the sale of any products developed by bioMérieux using our intellectual property.

In January 2005, we also entered into a license agreement with Corixa Corporation, or Corixa, and received the right to develop molecular diagnostic tests for approximately 50 potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancers. Pursuant to the terms of the agreement, we paid Corixa an initial access license fee of \$1.6 million and agreed to pay an additional \$3.2 million in two equal access fees of \$1.6 million on January 31, 2006 and January 31, 2007, unless we terminate the agreement prior to those dates. We expect to record the initial \$1.6 million license fee as an intangible asset which will be amortized over the underlying life of the patents or the term of our rights to these patents, whichever expires sooner. We also agreed to pay Corixa milestone payments totaling an additional \$2.0 million on a product-by-product basis based on the occurrence of certain regulatory and/or commercial events. Further, we agreed to pay Corixa additional milestone payments and royalties on net sales of any products developed by us using Corixa's technology.

In December 2004, we entered into a license agreement with AdnaGen AG, or AdnaGen, to gain access to technology that may help increase the accuracy of molecular diagnostic tests to detect prostate and other cancers. Under the terms of the agreement, we paid AdnaGen a license fee of \$1.0 million, and agreed to pay \$750,000 on the later of February 1, 2006 or upon issuance to AdnaGen of a patent containing valid claims that cover products licensed under the agreement. We recorded the \$1.0 million license fee as R&D expense in 2004 since we have not yet determined technological feasibility and do not currently have alternative future plans to use this technology other than for our prostate cancer development program. Upon the occurrence of certain clinical, regulatory and/or commercial events, we agreed to pay AdnaGen up to three milestone payments totaling an additional \$2.25 million. Further, we agreed to pay AdnaGen royalties on net sales of any products we develop using AdnaGen's technology.

In November 2004, we entered into an exclusive option agreement with Qualigen, Inc. to develop and commercialize a point-of-use NAT instrument based on Qualigen's FDA-approved FastPack immunoassay system. If successfully developed, the portable instrument would use our NAT technology to detect, at the point of sample collection, the presence of harmful microorganisms and genetic mutations. Under the terms of the agreement, we paid Qualigen \$1.0 million for an 18-month option to license, on an exclusive basis, Qualigen's technology to develop NAT assays for the clinical diagnostics, blood screening and industrial fields. During this period, we intend to evaluate the feasibility of adapting Qualigen's immunoassay platform to perform NAT using our proprietary technologies. If we exercise this option, at our sole discretion, then we have agreed to purchase shares of Qualigen preferred stock convertible into approximately 19.5% of Qualigen's then outstanding fully diluted common shares outstanding. The cost of acquiring this equity interest would vary between \$5.9 and \$7.0 million, depending on the timing of the option exercise. In addition, we may pay Qualigen up to \$3.0 million in license fees based on development milestones, and agreed to pay royalties on any product sales. We recorded the \$1.0 million option fee as an intangible asset which is being amortized over the 18-month evaluation period of the option or until execution of the license, whichever comes first.

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

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

Supply Agreements In February 2005, we entered into a Supply and Purchase Agreement with F. Hoffmann-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc., or Roche. Under this agreement, Roche will manufacture and supply DNA probes for human papillomavirus, or HPV. We will use these probes in molecular diagnostic assays. Pursuant to the agreement, we will pay Roche manufacturing fees of \$20.0 million within 90 days of February 15, 2005 and \$10.0 million within 10 days of the occurrence of certain future commercial events. We also agreed to pay Roche transfer fees for the HPV products.

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

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

REVENUES

We derive revenues from three primary sources: product sales, collaborative research revenue and royalty and license revenue. The majority of our revenues come from product sales, which consist primarily of sales of our NAT assays tested on our proprietary instruments that serve as the analytical platform for our assays. We recognize as collaborative research revenue payments we receive from Chiron for the products we provide under our collaboration agreement with Chiron prior to regulatory approval, and the payments we receive from Chiron, Bayer Corporation, or Bayer, and other collaboration partners, including the National Institutes of Health, or NIH, for research and development activities. Our royalty and license revenues reflect fees paid to us by third parties for the use of our proprietary technology. In 2004, product sales, collaborative research revenues and royalty and license revenues equaled 83%, 10% and 7%, respectively, of our total revenues of \$269.7 million.

Product Sales Our primary source of revenue is the sale of clinical diagnostic products in the United States, which include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During 2004, we shipped approximately 22 million tests for the diagnosis of a wide variety of infectious microorganisms, including those causing sexually transmitted diseases, or STDs, tuberculosis, strep throat, pneumonia and fungal infections. The principal customers for our clinical diagnostics products include large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

Since 1999, we have supplied NAT assays for use in screening blood donations intended for transfusion. Our primary blood screening assay detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments are marketed through our collaboration with Chiron under the Procleix and Ultrio trademarks. We recognize product sales from the manufacture and shipment of tests for screening donated blood at a contractual transfer price, through our collaboration with Chiron, to blood bank facilities located in the countries where our products have obtained governmental approvals. Blood screening product sales are then adjusted monthly

corresponding to Chiron's payment to us of amounts reflecting our ultimate share of net revenue from sales by Chiron to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Chiron to third-parties, less freight, duty and certain other adjustments specified in our agreement with Chiron, multiplied by our share of the net revenue. Our share of the net revenue was 43.0% with respect to sales of assays that include a test for HCV beginning the second quarter of 2002 (following FDA approval in February 2002) upon implementation of commercial pricing, through April 6, 2003, after which our share of net revenues from sales of assays that include a test for HCV was adjusted to 47.5%. Effective January 1, 2004, our share of net revenues from commercial sales of assays that include a test for HCV was permanently changed to 45.75% under our agreement with Chiron. With respect to commercial sales of blood screening assays under our collaboration with Chiron that do not include a test for HCV, such as possible future commercial tests for WNV, we will continue to receive reimbursement for our manufacturing costs plus 50% of net revenues. Our costs related to these products primarily include manufacturing costs.

Collaborative Research Revenue We have recorded revenues related to use of our blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue, because price restrictions applied to these products prior to FDA license approval in the United States and similar approvals in foreign countries. In 2004 and 2003, we recognized \$18.5 million and \$6.0 million, respectively, as collaborative research revenue through our collaboration with Chiron from deliveries of WNV tests on a "cost recovery" basis. Our NAT assay to detect WNV is currently being used in clinical trials under an Investigational New Drug, or IND, application. In 2004, we recognized \$1.4 million in reimbursements for expenses incurred for WNV. We expect to continue recognizing these sales as collaborative research revenue until FDA approval has been received, although there is no guarantee we ultimately will receive FDA approval.

In March 2003, we signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. In 2004, we recognized \$2.8 million in reimbursements for expenses incurred related to the development of this assay. We expect to receive further reimbursement from Chiron for certain costs incurred during the development of the Procleix Ultrio and WNV assays. In January 2004, we commenced clinical trials of the Procleix Ultrio assay in the United States on our TIGRIS instrument. In September 2004, we filed a BLA with the FDA for this assay.

We recognize collaborative research revenue over the term of our strategic alliance agreement with Chiron as reimbursable costs are incurred. The costs associated with the reported collaborative research revenue are based on fully burdened full time equivalent, or FTE, rates and are reflected in our statements of income under the captions "Research and development," "Marketing and sales" and "General and administrative," based on the nature of the costs. We do not separately track all of the costs applicable to our blood screening development collaboration with Chiron and, therefore, are not able to quantify all of the direct costs associated with the collaborative research revenue.

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

Royalty and License Revenue We recognize non-refundable up-front license fees over the performance period of the applicable agreement or at the time that we have satisfied all substantive performance obligations under such agreement. We also receive milestone payments for successful achievement of contractual development activities. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) we have earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement, and (iii) the fees are non-refundable. Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue on our balance sheet.

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

In December 2003, we entered into an agreement with Tosoh to cross-license intellectual property covering certain NAT technologies. The licenses, which were effective January 1, 2004, cover products in clinical diagnostics and other related fields. Under the agreement, Tosoh received non-exclusive rights to our proprietary Transcription-Mediated Amplification, or TMA, and rRNA technologies in exchange for two payments to us totaling \$7.0 million. These payments were recognized as revenue in the first quarter of 2004 as there were no additional obligations placed on us after the effective date of the contract and the transfer of rights to the technology. Further, Tosoh agreed to pay us royalties on worldwide sales of any future products that employ our technologies licensed by Tosoh. We also have gained access, in exchange for the payment of royalties, to Tosoh's patented Transcription Reverse-Transcription Concerted, or TRC, amplification and Intercalation Activating Fluorescence, or INAF, detection technologies for use with our real time TMA technology.

Under the strategic alliance agreement we entered into with Chiron in June 1998, we have responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Chiron has responsibility for marketing, distribution and service of the blood screening products worldwide. During the first quarter of 2004, we recognized as royalty and license revenue, a \$6.5 million milestone payment from Chiron as we commenced clinical trials of the Procleix Ultrio assay on our TIGRIS instrument in the United States. An additional payment of \$10.0 million is due to us in the future under the agreement if we obtain FDA approval of our Ultrio assay for use on the TIGRIS instrument. There is no guarantee we will achieve this milestone and receive any additional milestone payments under this agreement.

Cost of Product Sales Cost of product sales includes direct material, direct labor, and manufacturing overhead associated with the production of inventory on a standard cost basis. Indirect cost elements, which include manufacturing variances, purchase price variances, and allowances for scrap are also included as a component of cost of product sales, as well as certain related expenses, such as royalties, warranty, and instrument amortization.

In addition, we manufacture significant quantities of raw materials, development lots, and clinical trial lots of product prior to receiving FDA approval for commercial sale. During 2004 and 2003, our manufacturing facilities produced development lots for WNV and Procleix Ultrio assays. The majority of costs associated with these development lots are classified as research and development expense. The portion of a development lot that is manufactured to support In-Vitro Diagnostic, or IVD, sales abroad is charged to inventory and classified as cost of product sales upon shipment.

Our blood screening manufacturing facility has operated below its capacity and will continue to operate below its potential capacity for the foreseeable future. A portion of this available capacity is utilized for research and development activities as new product offerings are developed for commercialization. As a result, certain operating costs of our blood screening facility, together with other manufacturing costs for the production of pre-commercial development lot assays that are delivered under the terms of an IND application, are classified as research and development expense prior to FDA approval.

Effective January 1, 2004, our revenue sharing percentage with Chiron was reduced from 47.5% to 45.75%. This change, combined with higher instrument costs, including the amortization of our capitalized software development costs (which we began to amortize in 2004) and related service costs attributed to the general commercial launch of our TIGRIS instrument, contributed to lower 2004 gross margin percentage levels. In addition, our non-military customers currently utilize pooled blood screening samples for testing. We anticipate that requirements for smaller pool sizes or ultimately individual donor testing, if and when implemented, could result in lower gross margin rates, as additional tests would be required to deliver the sample results, unless a corresponding increase in sales pricing is implemented. We are not able to accurately predict the extent to which our gross margin may be affected as a result of smaller pool sizes or individual donor testing because we do not know the ultimate selling price that Chiron, our distributor, would charge to the end user if smaller pool sizes or individual donor testing is implemented.

Research and Development We invest significantly in research and development, or R&D, as part of our ongoing efforts to develop new products and technologies. Our R&D expenses include the development of proprietary products and instrument platforms, as well as expenses related to the co-development of new products and technologies in collaboration with our strategic partners. R&D spending is expected to increase in the future due to new product development, clinical trial costs and clinical manufacturing costs; however, we expect our R&D expenses as a percentage of total revenues to decline in future years. The timing of clinical trials and development manufacturing costs is variable and is affected by product development activities and the regulatory process.

In connection with our R&D efforts, we have various license agreements which provide us with rights to develop and market products using certain technologies and patent rights maintained by third parties. These agreements generally provide for a term that commences upon execution of the agreement and continues until expiration of the last patent related to the technologies covered by the license.

R&D expenses include the costs of raw materials, development lots and clinical trial lots of products that we manufacture. These costs are dependent on the status of projects under development and may vary substantially between quarterly or annual reporting periods. During 2005, we expect to incur further incremental costs associated with the manufacture of developmental lots and clinical trial lots for our blood screening products and with further development of our TIGRIS instrument. Collaborative research revenues associated with these types of incurred costs have at times been realized in a period later than when incurred due to the need for further clarity on the extent of reimbursable costs.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectibility of accounts receivable, valuation of inventories, long-lived assets including patent costs and capitalized software, and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

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

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

We manufacture our blood screening products according to Chiron's demand specifications and transfer/shipment of completed product to Chiron's virtual warehouse, which consists of various interim locations on our premises. Upon transfer/shipment of completed product to Chiron's virtual warehouse, we bill Chiron at a cost recovery transfer price, and Chiron remits payment in 30 days. We record amounts billed as deferred revenue until product shipment is made to Chiron's end-customers. Customer orders for the assay are received by Chiron and then communicated to our personnel who fulfill the orders and ship to Chiron's end-customers. Upon shipment to the end-customer, we recognize blood screening product sales at the transfer price and record cost of products sold at the cost of our assays. Blood screening product sales are adjusted upon our receipt of payment from Chiron of amounts reflecting our ultimate share of net sales by Chiron of these products, less the transfer price revenues previously paid.

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

Product sales also include the sales or rental value associated with the delivery of our proprietary integrated instrument platforms that perform our NAT assays. Generally, we provide our instrumentation to clinical laboratories and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, we recover the cost of providing the instrumentation in the amounts we charge for our diagnostic assays. The costs associated with an instrument are charged to costs of product sales on a straight-line basis over the estimated life of an instrument, which ranges from three to five years; generally, three years for luminometers and DTS 400/800 systems, and five years for TIGRIS and DTS 800/1600 systems. The costs to maintain these systems in the field are charged to operations as incurred.

We sell our instrumentation to Chiron for use in blood screening and record these instrument sales upon delivery since Chiron is responsible for the placement, maintenance and repair of the units with their customers. Occasionally, we sell instrumentation to our clinical diagnostics customers. We record sales of these instruments as product sales upon delivery and receipt of customer acceptance. Prior to delivery, each instrument is extensively tested to meet Company and FDA specifications, and is shipped fully assembled. Customer acceptance of our instrument systems requires installation and training by our technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating, and testing the instrumentation.

We record as collaborative research revenue shipments of our blood screening products in the United States and other countries in which the products have not received regulatory approval. We do this because price restrictions apply to these products prior to FDA marketing approval in the United States and similar approvals in foreign countries. As commercial pricing is implemented, we classify sales of these products as product sales in our financial statements.

We recognize collaborative research revenue over the term of various collaboration agreements as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to that agreement. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the contracts. Non-refundable license fees are recognized over the related performance period or at the time that we have satisfied all performance obligations related to the agreement. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) we have earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement, and (iii) the fees are non-refundable. Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue on our balance sheet.

We recognize royalty revenue related to the manufacture, sale or use of our products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the applicable licensee.

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

Valuation of Inventories We record valuation adjustments to our inventory balances for estimated excess and obsolete inventory equal to the difference between the cost of such inventory and the estimated market value based upon assumptions about future product demand and the shelf-life and expiration dates for finished goods and materials used in the manufacturing process. We operate in an environment

that is regulated by the FDA and other governmental agencies that may place restrictions on our ability to sell our products into the marketplace if certain compliance requirements are not met. We have made assumptions that are reflected in arriving at our net inventory value based on the information currently available to us. If future product demand, regulatory constraints or other market conditions are less favorable than those projected by management, additional inventory valuation reserves may be required.

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

Valuation of Goodwill We assess the impairment of goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Impairment is reviewed at least annually, generally in the fourth quarter of each year.

Factors we consider important which could trigger an impairment, include the following:

- Significant underperformance relative to historical or projected future operating results;
- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- Significant negative industry or economic trends;
- Significant declines in our stock price for a sustained period; and
- Decreased market capitalization relative to net book value.

When there is an indication that the carrying value of goodwill may not be recoverable based upon the existence of one or more of the above indicators, an impairment loss is recognized if the carrying amount exceeds its fair value.

Capitalized Software Costs We capitalize costs incurred in the development of computer software related to products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product. At December 31, 2004, capitalized software development costs related to our TIGRIS instrument totaled \$23.5 million, net of accumulated amortization. We completed beta evaluations of this instrument for clinical diagnostic applications and undertook initial beta trials for blood screening applications before we completed a clinical trial for a diagnostic application in June 2003. In December 2003, we received approval from the FDA for testing certain STDs on our TIGRIS instrument. We initiated clinical trials of our Procleix Ultrio assay on our TIGRIS instrument for a blood screening application in January 2004 and filed a BLA with the FDA for this assay in the third quarter of 2004. If we are not able to successfully deliver this instrument to the marketplace and attain customer acceptance, the asset could be impaired and an adjustment to the carrying value of this asset would be considered by management at that time.

In accordance with Statement of Financial Accounting Standards, or SFAS, No. 86, "Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed," we began amortizing the capitalized software costs on a straight-line basis over 120 months during May 2004, coinciding with the general release of TIGRIS instruments to our customers.

Income Taxes Through December 31, 2002, we were included in the consolidated federal and in various combined state income tax returns of our former parent company, Gen-Probe Holding Company, Inc., formerly known as Chugai Pharma U.S.A., Inc. Pursuant to a tax sharing agreement with Gen-Probe Holding Company, we generally were allocated an amount of the consolidated tax liability

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

equal to the tax that would have been applicable if computed separately. At December 31, 2004, we had net deferred tax liabilities of \$1.5 million, which relate to capitalized costs expensed for tax purposes and other items. These amounts are offset by research and investment credits filed in our tax returns, and timing differences arising from the recording of deferred revenue and certain reserves and accruals.

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

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

RESULTS OF OPERATIONS

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

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

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

(Percentages have been rounded to the nearest whole percentage)

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

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

COLLABORATIVE RESEARCH REVENUE Collaborative research revenue increased \$11.7 million, or 76%, to \$27.1 million in 2004, from \$15.4 million in 2003. The increase was primarily the result of a \$12.6 million increase in firm support commitment payments in connection with the WNV tests provided to United States customers through our collaboration with Chiron, and a \$1.4 million increase in revenue for reimbursement from Chiron for WNV development costs. This increase was partially offset by a \$1.9 million decrease in revenue from the NIH as our WNV funding was completed during 2004 and a \$1.2 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay.

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

ROYALTY AND LICENSE REVENUE Royalty and license revenue increased \$16.9 million, or 545%, to \$20.0 million in 2004, from \$3.1 million in 2003. The increase was principally attributed to (i) \$7.0 million in license fees earned from Tosoh as part of our non-exclusive licensing agreement relating to NAT technologies effective in January 2004, and (ii) a \$6.5 million milestone payment from Chiron as we began clinical trial testing of the Procleix Ultrio assay on our fully automated TIGRIS instrument in the United States. Further, we recognized \$3.2 million of license revenue from Bayer during 2004 for the licensing of rights to certain patented technology.

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

COST OF PRODUCT SALES Cost of product sales increased \$14.4 million to \$59.9 million, or 27% of product sales revenues in 2004, from \$45.5 million, or 24% of product sales revenues in 2003. The \$14.5 million increase in cost of sales was principally attributed to the volume increase in product sales, higher allowances for scrap expense and the amortization of capitalized software development costs related to our TIGRIS instrument. Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales are also affected by manufacturing efficiencies, allowances for scrap or expired materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

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

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

We anticipate that requirements for smaller pool sizes or ultimately individual donor testing, if and when implemented, could result in lower gross margin rates as additional tests would be required to deliver the sample results, unless a corresponding increase in sales pricing structure is implemented. We are not able to accurately predict the extent to which our gross margin may be negatively affected as a result of smaller pool sizes or individual donor testing because we do not know the ultimate selling price that Chiron, our distributor, would charge to the end user if smaller pool sizes or individual donor testing is implemented.

RESEARCH AND DEVELOPMENT Our R&D expenses include salaries and other personnel-related expenses, temporary personnel, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. R&D expenses increased \$4.9 million, or 8%, to \$68.5 million, or 25% of total revenues, in 2004, from \$63.6 million, or 31% of total revenues, in 2003. Increased R&D spending was comprised of a \$9.0 million increase in expenses resulting from higher staffing levels to support product development projects and clinical trial efforts, a \$2.2 million increase in expenses related to clinical trials for blood screening products, a \$1.6 million increase in outside development research due to our aggregate license fees paid to DiagnoCure and AdnaGen and a \$1.2 million increase in R&D expenses from our subsidiary, Molecular Light Technology Limited (acquired in August 2003). These increases were mostly offset by a \$9.3 million decrease in development lot production and lower per unit costs.

MARKETING AND SALES Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased \$4.6 million, or 20%, to \$27.2 million, or 10% of total revenues, in 2004, from \$22.6 million, or 11% of total revenues, in 2003. The increased spending principally included a \$3.7 million increase in salaries, benefits, commissions and other personnel related costs in our marketing, sales, and technical service organization to support APTIMA market expansion and TIGRIS instrument commercialization, together with a \$0.6 million increase for advertising and promotional costs related to the marketing launch of our TIGRIS instrument.

GENERAL AND ADMINISTRATIVE Our general and administrative, or G&A, expenses include personnel costs for finance, legal, business development, public relations and human resources, as well as professional fees, such as expenses for legal, patents and auditing services. G&A expenses increased \$8.4 million, or 36%, to \$31.6 million, or 12% of total revenues, in 2004 from \$23.2 million, or 11% of total revenues, in 2003. The increased spending included a \$3.0 million increase in salaries, benefits and other expenses resulting from higher staffing levels, including \$1.0 million in expenses from our majority owned subsidiary, Molecular Light Technology Limited; a \$3.6 million increase in patent and legal related expenses, including the costs of our ongoing arbitration with Bayer; and a \$0.7 million non-cash compensation charge related to the departure of a former executive.

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

INCOME TAX EXPENSE Income tax expense increased to \$30.0 million, or 35.5% of pretax income, during 2004, from \$19.8 million, or 35.9% of pretax income, in 2003. The slight decrease in our effective tax rate in 2004 was principally attributed to an increase in tax-exempt interest income, partially offset by higher profits taxed at the combined federal and state statutory tax rate of approximately 41%.

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

(Percentages have been rounded to the nearest whole percentage)

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

COLLABORATIVE RESEARCH REVENUE Collaborative research revenue increased \$4.4 million, or 40%, to \$15.4 million in 2003, from \$11.0 million in 2002. The increase was primarily the result of a \$4.2 million increase in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay. Additionally, revenues increased by \$1.8 million in 2003 due to additional funds received from the NIH in November 2003 to develop a NAT assay for the detection of WNV. These increases were partially offset by a \$1.1 million decrease in firm support commitment payments in connection with Procleix tests provided to United States customers through our collaboration with Chiron.

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

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

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

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

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

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

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

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

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

LIQUIDITY AND CAPITAL RESOURCES (In thousands)

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

Historically, we have financed our operations through cash from operations, cash received from collaborative research agreements, royalty and license fees, and cash from capital contributions. At December 31, 2004, we had \$193.8 million of cash and cash equivalents and short-term investments.

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

The \$18.9 million increase in our investing activities during 2004 included a net \$17.0 million payment to Vysis for a fully paid up license to eliminate future royalty obligations under the patent covered by the license. In addition, our investing activities included a \$13.8 million increase in capital expenditures, partially offset by a \$5.2 million decrease in net purchases of short-term investments. Our 2004 growth in capital expenditures was primarily due to the construction of our new building and costs of our new Enterprise Resource Planning, or ERP, system implementation. Our expenditures for capital additions vary based on the stage of certain development projects and may increase in the future related to the timing of development of new product opportunities and to support expansion of our facilities in connection with those opportunities. The average age of our property, plant and equipment is approximately five years, which provides us flexibility in planning capital expenditures.

The \$5.6 million increase in net cash provided by financing activities during 2004 was principally attributed to a \$3.2 million increase in employee purchases of our common stock made through our Employee Stock Purchase Plan, or ESPP, and a \$2.4 million increase in proceeds from the exercise of stock options. On a going-forward basis, cash from financing activities will be affected by proceeds from the exercise of stock options and receipts from sales of stock under our ESPP. We expect fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock, along with other factors.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2005, under which we may borrow up to \$10.0 million, subject to a "borrowing base formula," at the bank's prime rate, or at LIBOR plus 1.0%. We have not taken advances against the line of credit since its inception. The line of credit agreement requires us to comply with various financial and restrictive covenants. At December 31, 2004, we were in compliance with all covenants.

In July 2004, we commenced construction of an additional building to expand our main San Diego campus. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 190,000 square feet built-out with interior improvements. The additional space that will not initially be built-out will allow for future expansion. The first phase of this project is currently estimated to cost approximately \$44.0 million, of which \$6.3 million was capitalized to construction in-progress during 2004. These costs are being capitalized as incurred and depreciation will commence upon our completion and use, which is planned for early 2006. These amounts are not included in the chart below.

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

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

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

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

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

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

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

(3) Does not include amounts relating to our obligations under our collaboration with Chiron, pursuant to which both parties have obligations to each other. We are obligated to manufacture and supply our blood screening assay to Chiron, and Chiron is obligated to purchase all of the quantities of this assay specified on a 90-day demand forecast, due 90 days prior to the date Chiron intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

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

Our collaboration commitments include:

- *DiagnoCure*. As part of our collaboration to develop a molecular diagnostic test that detects a new gene marker for prostate cancer, approximately \$5.7 million remains to be paid to DiagnoCure pursuant to this obligation.
- *Corixa*. As part of our license to develop molecular diagnostic tests for approximately 50 potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancer, approximately \$5.2 million remains to be paid to Corixa.
- *Qualigen*. If we exercise our option to develop a point-of-use NAT instrument, we will purchase an equity interest in Qualigen ranging from \$5.9 to \$7.0 million. Further, we may pay Qualigen up to \$3.0 million based on development milestones.
- *AdnaGen*. As part of our license to technology that may help increase the accuracy of molecular diagnostic tests for prostate and other cancers, we may pay AdnaGen up to \$3.0 million based on achievement of certain milestones.

Our supply commitments include:

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

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

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

We may from time to time consider the acquisition of businesses and/or technologies complementary to our business. We could require debt financing if we were to engage in a material acquisition in the future. In August 2003, we filed a Form S-3 shelf registration statement with the SEC relating to the possible future sale of up to an aggregate of \$150 million of debt or equity securities.

STOCK OPTIONS

Option Program Description Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our program primarily consists of three broad-based plans under which stock options are granted to employees, directors and other service providers. Substantially all of our employees have historically participated in our stock option program.

All stock option grants are made with the approval of the Compensation Committee of the Board of Directors. Additional information regarding our stock option plans for 2004, 2003 and 2002 is provided in our consolidated financial statements. See “Notes to Consolidated Financial Statements, Note 8 – Stockholders’ Equity.”

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

Summary of Option Activity (Shares in thousands)

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

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

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

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

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

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our financial instruments that are exposed to changes in interest rates.

Foreign Currency Exchange Risk Although the majority of our revenue is realized in United States dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. The functional currency of our majority owned subsidiary is the British pound. Accordingly, the accounts of these operations are translated from the local currency to the United States dollar using the current exchange rate in effect at the balance sheet date for the balance sheet accounts, and using the average exchange rate during the period for revenue and expense accounts. The effects of translation are recorded in accumulated other comprehensive income as a separate component of stockholders' equity.

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

CHANGES IN AND DISAGREEMENTS WITH INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

CONTROLS AND PROCEDURES

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

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

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

Management's Report on Internal Control Over Financial Reporting Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004 based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under the framework in Internal Control - Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

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

Report of Independent Registered Public Accounting Firm, Ernst & Young LLP

The Board of Directors and Stockholders

We have audited the accompanying consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gen-Probe Incorporated at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Gen-Probe Incorporated's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 10, 2005 expressed an unqualified opinion thereon.



San Diego, California

February 10, 2005

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting, Ernst & Young LLP

The Board of Directors and Stockholders

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Gen-Probe Incorporated maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of sponsoring organization of the Treadway Commission (the COSO criteria). Gen-Probe Incorporated's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Gen-Probe Incorporated maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Gen-Probe Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Gen-Probe Incorporated as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 of Gen-Probe Incorporated and our report dated February 10, 2005 expressed an unqualified opinion thereon.

The signature of Ernst & Young LLP is written in a cursive, handwritten style in black ink.

San Diego, California

February 10, 2005

Consolidated Balance Sheets (IN THOUSANDS, EXCEPT PER SHARE DATA)

DECEMBER 31	2004	2003
CURRENT ASSETS:		
Cash and cash equivalents	\$ 25,498	\$ 35,973
Short-term investments	168,328	120,333
Trade accounts receivable, net of allowance for doubtful accounts of \$664 and \$717 at December 31, 2004 and 2003, respectively	21,990	15,158
Accounts receivable – other	3,136	2,555
Inventories	27,308	13,676
Deferred income taxes	7,725	10,979
Prepaid expenses and other current assets	13,964	10,203
Total current assets	267,949	208,877
Property, plant and equipment, net	76,651	65,478
Capitalized software	23,466	24,872
Goodwill	18,621	18,621
Other assets	24,395	6,893
Total assets	\$ 411,082	\$ 324,741
CURRENT LIABILITIES:		
Accounts payable	6,729	9,250
Accrued salaries and employee benefits	11,912	11,670
Other accrued expenses	4,451	6,085
Income tax payable	1,188	6,191
Deferred revenue	9,467	6,681
Total current liabilities	33,747	39,877
Deferred income taxes	9,187	6,850
Deferred revenue	5,000	5,667
Deferred rent	309	323
Minority interest	1,810	1,649
COMMITMENTS AND CONTINGENCIES:		
Stockholders' equity:		
Preferred stock, \$.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$.0001 par value per share; 200,000,000 shares authorized, 50,035,490 and 48,721,560 shares issued and outstanding at December 31, 2004 and 2003, respectively	5	5
Additional paid-in capital	248,767	212,586
Deferred compensation	(1,104)	(538)
Accumulated other comprehensive income	807	343
Retained earnings	112,554	57,979
Total stockholders' equity	361,029	270,375
Total liabilities and stockholders' equity	\$ 411,082	\$ 324,741

See accompanying notes to consolidated financial statements.

Consolidated Statements of Income (IN THOUSANDS, EXCEPT PER SHARE DATA)

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

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows (IN THOUSANDS)

YEARS ENDED DECEMBER 31	2004	2003	2002
OPERATING ACTIVITIES			
Net income	\$ 54,575	\$ 35,330	\$ 13,007
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	18,239	15,822	17,784
Stock compensation charges	1,142	149	—
Loss on disposal of property and equipment	377	102	308
Deferred rent	(14)	(4)	30
Stock option income tax benefits	14,035	4,387	—
Deferred revenue	2,119	(1,085)	1,221
Deferred income taxes	5,567	(2,239)	1,106
Minority interest	(13)	37	—
Changes in assets and liabilities:			
Accounts receivable	(6,774)	(2,164)	6,219
Inventories	(13,621)	(688)	(753)
Prepaid expenses and other current assets	(3,761)	(5,089)	(531)
Accounts payable	(2,535)	310	58
Accrued salaries and employee benefits	242	2,710	1,920
Other accrued expenses	(2,329)	(259)	(1,059)
Income tax payable	(4,965)	5,297	2,927
Net cash provided by operating activities	62,284	52,616	42,237
INVESTING ACTIVITIES			
Proceeds from sales and maturities of short-term investments	159,301	42,722	—
Purchases of short-term investments	(206,822)	(95,421)	(64,842)
Purchases of property, plant and equipment	(26,021)	(12,238)	(12,616)
Capitalization of license fees	(19,026)	(3,000)	—
Capitalization of software development costs	(270)	(2,070)	(3,011)
Capitalization of patent costs	(540)	(635)	(678)
Cash paid for acquisition of Molecular Light Technology shares, net of cash acquired	(376)	(4,133)	—
Other assets	42	(12)	400
Net cash used in investing activities	(93,712)	(74,787)	(80,747)

Continued on next page.

Consolidated Statements of Cash Flows (IN THOUSANDS)

(continued)

YEARS ENDED DECEMBER 31	2004	2003	2002
FINANCING ACTIVITIES			
Proceeds from issuance of common stock	20,438	14,888	—
Principal payments on long-term debt	—	—	(12,000)
Capital contribution from merger with Gen-Probe Holding	—	—	75,878
Net cash provided by financing activities	20,438	14,888	63,878
Effect of exchange rate changes on cash	515	138	—
Net increase (decrease) in cash and cash equivalents	(10,475)	(7,145)	25,368
Cash and cash equivalents at the beginning of year	35,973	43,118	17,750
Cash and cash equivalents at the end of year	\$ 25,498	\$ 35,973	\$ 43,118
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid for:			
Interest	\$ 34	\$ 63	\$ 754
Income taxes	\$ 16,030	\$ 11,913	\$ 2,104
Non-cash financing activities:			
Contribution of non-cash items from merger with Gen-Probe Holding	\$ —	\$ —	\$ 10,646

See accompanying notes to consolidated financial statements.

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, 2001	47,600	\$ 5	\$ 106,100	\$ —	\$ 60	\$ 9,642	\$ 115,807
Capital contribution from merger with Gen-Probe Holding	—	—	86,524	—	—	—	86,524
Comprehensive income:							
Net income	—	—	—	—	—	13,007	13,007
Unrealized gains on short-term investments, net of income tax expense of \$53	—	—	—	—	240	—	240
Comprehensive income							13,247
BALANCE AT DECEMBER 31, 2002	47,600	5	192,624	—	300	22,649	215,578
Common shares issued from							
exercise of stock options	1,083	—	14,301	—	—	—	14,301
Purchase of common shares through							
employee stock purchase plan	35	—	587	—	—	—	587
Issuance of common shares to board members	4	—	87	—	—	—	87
Deferred compensation related to grant of restricted							
stock awards	—	—	600	(600)	—	—	—
Amortization of deferred compensation	—	—	—	62	—	—	62
Stock option income tax benefits	—	—	4,387	—	—	—	4,387
Comprehensive income:							
Net income	—	—	—	—	—	35,330	35,330
Unrealized gains on short-term investments, net of income tax expense of \$61	—	—	—	—	43	—	43
Comprehensive income							35,373
BALANCE AT DECEMBER 31, 2003	48,722	5	212,586	(538)	343	57,979	270,375
Common shares issued from							
exercise of stock options	1,178	—	16,672	—	—	—	16,672
Purchase of common shares through							
employee stock purchase plan	132	—	3,766	—	—	—	3,766
Issuance of common shares to board members	3	—	140	—	—	—	140
Deferred compensation related to grant of restricted							
stock awards	—	—	839	(839)	—	—	—
Amortization of deferred compensation	—	—	—	273	—	—	273
Stock option compensation expense for modification							
of stock option awards	—	—	729	—	—	—	729
Stock option income tax benefits	—	—	14,035	—	—	—	14,035
Comprehensive income:							
Net income	—	—	—	—	—	54,575	54,575
Unrealized losses on short-term investments, net of income tax benefits of \$17	—	—	—	—	(313)	—	(313)
Foreign currency translation adjustment	—	—	—	—	777	—	777
Comprehensive income							55,039
BALANCE AT DECEMBER 31, 2004	50,035	\$ 5	\$ 248,767	\$ (1,104)	\$ 807	\$ 112,554	\$ 361,029

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1 ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization Gen-Probe Incorporated (“Gen-Probe” or the “Company”) is engaged in developing, manufacturing and marketing nucleic acid probe-based products used for the clinical diagnosis of human diseases and for screening donated human blood. Gen-Probe’s principal customers are large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

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

In August 2003, the Company paid approximately \$7.2 million in cash to acquire an additional 65.6% of the outstanding shares of Molecular Light Technology Limited (“MLT”), a privately held company located in Cardiff, Wales. In August 2004, the Company paid \$376,000 plus accrued interest, in cash, to acquire an additional 3.42% of the outstanding shares, giving the Company a total ownership of 86% when added to the amount previously held. As such, the Company owns more than 50% and has the ability to control the operations of this subsidiary and, therefore, has consolidated MLT with the Company since August 2003. MLT is a biotechnology company from which Gen-Probe licenses chemiluminescent technology it uses in its Hybridization Protection Assay (“HPA”) and dual kinetic assay (“DKA”). Gen-Probe is the exclusive licensee of the MLT technology for disease testing using nucleic acid hybridization. The acquisition was accounted for under the purchase method of accounting in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 141 “Business Combinations.”

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

Principles of Consolidation The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales and Services, Inc., Gen-Probe Canada, Inc., Gen-Probe UK Limited and Molecular Light Technology Limited and its subsidiaries. MLT and its subsidiaries are consolidated into the Company’s financial statements one month in arrears. All intercompany transactions and balances have been eliminated in consolidation.

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

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.

Notes to Consolidated Financial Statements (continued)

Foreign Currencies The functional currency of the Company's majority owned subsidiaries, GPUK Limited and MLT (and its subsidiaries), is the British pound. Accordingly, all balance sheet accounts of these subsidiaries are translated into United States dollars using the exchange rate in effect at the balance sheet date, and revenues and expenses are translated using the average exchange rates in effect during the period. The gains and losses from foreign currency translation of these subsidiary's financial statements are recorded directly as a separate component of stockholders' equity under the caption "Accumulated other comprehensive income."

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

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

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

Concentration of Credit Risk The Company sells its products primarily to established large reference laboratories, public health laboratories and hospitals. Credit is extended based on an evaluation of the customer's financial condition and generally collateral is not required.

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. The Company limits its exposure to credit loss by placing its cash with high credit quality financial institutions. The Company generally invests its excess cash in mortgage-backed securities, investment-grade corporate and municipal bonds.

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

Collectibility of Accounts Receivable The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. Credit losses historically have been minimal and within management's expectations. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of the Company's ability to make payments, additional allowances would be required.

Stock-Based Compensation The Company records compensation expense for employee stock-based compensation using their intrinsic value on the date of grant pursuant to Accounting Principles Board Opinion 25 (“APB”) No. 25, “Accounting for Stock Issued to Employees.” Under the intrinsic value method, compensation cost for employee stock awards is recognized as the excess, if any, of the deemed fair value for financial reporting purposes of the Company’s common stock on the date of grant over the amount an employee must pay to acquire the stock. Because the Company establishes the exercise price based on the fair market value of the Company’s stock at the date of grant, the stock options have no intrinsic value upon grant, and therefore no expense is recorded. Each quarter, the Company reports the potential dilutive impact of stock options in its diluted earnings per common share using the treasury-stock method. Out-of-the-money stock options (i.e., the average stock price during the period is below the strike price of the stock option) are not included in diluted earnings per share.

As required under SFAS No. 123, “Accounting for Stock-Based Compensation,” the pro forma effects of stock-based compensation on net income and earnings per share have been estimated at the date of grant using the minimum value option pricing model from the stock option plan inception date in 2000 through September 15, 2002 and the Black-Scholes option-pricing model for all option grants made subsequent to that date. The following weighted average assumptions were used:

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

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

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no restrictions and are fully transferable and negotiable in a free trading market. The Black-Scholes model does not consider the employment, transfer or vesting restrictions that are inherent in the Company’s

employee stock options. Use of an option valuation model, as required by SFAS No. 123, includes highly subjective assumptions based on long-term predictions, including the expected stock price volatility and average life of each stock option grant.

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

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

YEARS ENDED DECEMBER 31	2004	2003	2002
Net income:			
As reported	\$ 54,575	\$ 35,330	\$ 13,007
Stock-based employee compensation expense included in reported net income, net of related tax effects	590	37	—
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(10,958)	(3,092)	(792)
Pro forma net income	\$ 44,207	\$ 32,275	\$ 12,215
Net income per share:			
As reported			
Basic	\$ 1.10	\$ 0.74	\$ 0.27
Diluted	\$ 1.06	\$ 0.72	\$ 0.27
Pro forma			
Basic	\$ 0.89	\$ 0.67	\$ 0.26
Diluted	\$ 0.86	\$ 0.66	\$ 0.26

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

Notes to Consolidated Financial Statements (continued)

Deferred compensation for restricted stock awards issued to the Company's chief executive officer has been determined in accordance with SFAS No. 123 as the fair value of the consideration received and is being amortized to expense on a straight-line basis over the vesting period. During the year ended December 31, 2004, the Company recorded an option-related non-cash compensation charge of approximately \$729,000 related to the departure of a former executive.

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

The Company manufactures its blood screening products according to Chiron's demand specifications and transfer/shipments of completed product to Chiron's virtual warehouse, which consists of various interim locations on Gen-Probe's premises. Upon transfer/shipment of completed product to Chiron's virtual warehouse, the Company bills Chiron at a cost recovery transfer price, and Chiron remits payment in 30 days. The Company records such amounts billed as deferred revenue until shipment to Chiron's end-customers. Customer orders for the assay are received by Chiron and then communicated to Company personnel who fulfill the orders and ship to Chiron's end-customers. Upon shipment to the end-customer, the Company recognizes blood screening product sales at the cost recovery transfer price and records cost of products sold at the cost of the assays. Blood screening product sales are adjusted upon the Company's receipt of payment from Chiron of amounts reflecting its ultimate share of net sales by Chiron of these products, less the cost recovery transfer price revenues previously paid.

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

The Company sells its instrumentation to Chiron for use in blood screening and records these instrument sales upon delivery since Chiron is responsible for the placement, maintenance and repair of the units with their customers. Occasionally, the Company sells instrumentation to its clinical diagnostics customers. The Company records sales of these instruments as product sales upon delivery and customer acceptance. Prior to delivery, each instrument is extensively tested to meet Company and FDA specifications, and is shipped fully assembled. Customer acceptance of the Company's instrument systems requires installation and training by the Company's technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating, and testing the instrumentation.

The Company records as collaborative research revenue shipments of its blood screening products in the United States and other countries in which the products have not received regulatory approval. This is done because price restrictions apply to these products prior to FDA marketing approval in the United States and similar approval in foreign countries. Once commercial pricing is implemented, the Company then classifies sales of these products as product sales in its financial statements.

The Company recognizes collaborative research revenue over the term of various collaboration agreements as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to that agreement. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the contracts. Non-refundable license fees are recognized over the related performance period or at the time that the Company has satisfied all performance obligations related to the agreement. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) the Company has earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement and (iii) the fees are non-refundable. Any amounts received prior to satisfying the Company's revenue recognition criteria are recorded as deferred revenue.

Royalty revenue is recognized related to the manufacture, sale or use of the Company's products or technologies under license arrangements with third parties. For those arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and adjusts for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenue upon receipt of royalty statements from the applicable licensee.

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

The Company does not separately track the total costs applicable to collaborative research revenue as there is not a distinction between the Company's internal development activities and the development efforts made pursuant to agreements with third parties. The costs applicable to the blood screening development collaboration are reflected in the statements of operations under the captions "Research and development," "Marketing and sales" and "General and administrative" based on the nature of the costs. The costs incurred related to collaborative research revenue have exceeded the amounts recorded as revenue for all periods presented.

Shipping and Handling Expenses Shipping and handling expenses are included in cost of product sales and totaled approximately \$2,569,000, \$2,258,000, and \$1,780,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Inventories Inventories are stated at the lower of cost (first-in, first-out) or market. The estimated reserve is based on management's review of inventories on hand compared to estimated future usage and sales, shelf-life and assumptions about the likelihood of obsolescence.

Patent Costs The Company capitalizes the costs incurred to file and prosecute patent applications. The Company amortizes these costs on a straight-line basis over the lesser of the remaining useful life of the related technology or eight years. At December 31, 2004 and 2003, capitalized patent costs, which have been included in "Other assets" on the consolidated balance sheet, totaled approximately \$1,243,000 and \$1,691,000, respectively, net of accumulated amortization. The Company expenses all costs related to abandoned patent applications.

Capitalized Software Costs The Company capitalizes costs incurred in the development of computer software related products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product of ten years.

Notes to Consolidated Financial Statements (continued)

Long-Lived Assets Property, plant and equipment and intangible assets with definite useful lives are stated at cost. Depreciation of property, plant and equipment is provided using the straight-line method over the estimated useful lives of the assets as follows:

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

Depreciation expense was \$14,497,000, \$14,380,000 and \$15,632,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Amortization of leasehold improvements is provided over the shorter of the remaining life of the lease or estimated useful life of the asset. The costs of other purchased intangibles are amortized over their estimated useful lives. Goodwill, less the amount allocated to in-process technology, was being amortized over 40 years through December 31, 2001.

Impairment of Long-Lived Assets The Company adopted SFAS No. 142, "Goodwill and Other Intangible Assets," at the beginning of 2002, which prohibits the amortization of goodwill and intangible assets with indefinite useful lives. SFAS No. 142 requires that these assets be reviewed for impairment at least annually. The Company completed its impairment test in the fourth quarter of 2004 and determined that no impairment loss was necessary. If the assets were considered to be impaired, the impairment charge would be the amount by which the carrying value of the assets exceeds the fair value of the assets.

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2004.

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

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

Research and Development Research and development costs are expensed as incurred.

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

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

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

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

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

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

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB No. 25’s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123(R)’s fair value method will have a significant impact on the Company’s statements of income, although it will have no impact on the Company’s overall financial position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in Note 1 to the consolidated financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While the Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), the amount of operating cash flows recognized in prior periods for such excess tax deductions were \$14,035,000, \$4,387,000, and \$0 for the years ended December 31, 2004, 2003 and 2002, respectively.

Notes to Consolidated Financial Statements (continued)

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

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

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

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

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

2 BALANCE SHEET INFORMATION

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

Inventories

DECEMBER 31	2004	2003
Raw materials and supplies	\$ 5,345	\$ 5,874
Work in process	10,429	3,118
Finished goods	11,534	4,684
	\$ 27,308	\$ 13,676

Property, plant and equipment

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

Other assets

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

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

3 SHORT-TERM INVESTMENTS

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

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

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

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

4 INTANGIBLE ASSETS BY ASSET CLASS AND RELATED ACCUMULATED AMORTIZATION

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

	DECEMBER 31					
	2004			2003		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	\$ 25,142	\$ 1,676	\$ 23,466	\$ 24,872	\$ —	\$ 24,872
Patents	15,305	14,062	1,243	14,764	13,073	1,691
Purchased intangible assets	33,636	31,994	1,642	33,636	31,658	1,978
License fees	22,026	752	21,274	3,000	36	2,964
Total	\$ 96,109	\$ 48,484	\$ 47,625	\$ 76,272	\$ 44,767	\$ 31,505
Goodwill	\$ 26,298	\$ 7,677	\$ 18,621	\$ 26,298	\$ 7,677	\$ 18,621

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

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

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

Notes to Consolidated Financial Statements (continued)

In September 2004, the Company entered into a Settlement Agreement and an Amendment to its Non-exclusive License Agreement with Vysis Inc. ("Vysis") under which the Company has withdrawn its patent litigation against Vysis and agreed to pay Vysis an aggregate of \$22,500,000. This aggregate amount includes \$20,500,000 for a fully paid up license to eliminate all future royalty obligations of the Company to Vysis under the Collins patent covered by the license, and \$2,000,000 for a fully paid-up, royalty-free license in additional fields covered by the Collins patent. The license now covers current and future products in the field of infectious diseases as well as potential products in all other fields. Chiron, the Company's blood screening partner, has reimbursed the Company \$5,474,000 of the \$20,500,000 allocated to the cost of the fully paid-up license for the current field, commensurate with its obligation to reimburse the Company a portion of the royalties paid by the Company to Vysis on blood screening products. The Company capitalized the \$17,026,000 net payment (\$22,500,000 less Chiron's \$5,474,000 reimbursement) as an intangible asset which is being amortized to cost of goods sold over the patent's remaining economic life of 135 months.

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

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

YEARS ENDED DECEMBER 31	Amortization Expense
2005	\$ 5,969
2006	5,086
2007	4,834
2008	4,729
2009	4,675
Thereafter	22,332
Total	\$ 47,625

5 LONG-TERM DEBT

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

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

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

6 RELATED PARTY TRANSACTIONS

The Company recorded royalty expense to MLT of \$1,451,000 and \$2,467,000 for the years ended December 31, 2003 and 2002, respectively, prior to the Company's acquisition of a majority ownership interest in MLT in August 2003. All royalty expense incurred by the Company subsequent to the acquisition has been eliminated in the consolidated financial statements.

7 INCOME TAXES

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

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

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

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

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

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

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

Notes to Consolidated Financial Statements (continued)

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

At December 31, 2004, the Company also had California research and development credit carryforwards of approximately \$3,716,000, which do not expire. In accordance with the Internal Revenue Code, the Company's use of its credit carryforwards could be limited in the event of certain cumulative changes in the Company's stock ownership.

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

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

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

8 STOCKHOLDERS' EQUITY

On May 28, 2004, the Company's stockholders approved an increase in the authorized number of shares of common stock under the Company's Certificate of Incorporation from 100,000,000 to 200,000,000 shares.

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

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

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

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

On September 16, 2002, the Company adopted a stockholder rights plan that could discourage, delay or prevent an acquisition of the Company under certain circumstances. The plan was amended by the Board of Directors on November 20, 2003. The rights plan provides for preferred stock purchase rights attached to each share of our common stock, which will cause substantial dilution to a person or group acquiring 15% or more of our stock if the acquisition is not approved by our Board of Directors. In connection with the rights plan, the Company declared a dividend of one preferred share purchase right for each outstanding share of common stock of the Company outstanding at the close of business on September 26, 2002, which automatically adjusted to one-half of a right as a result of the 100% stock dividend paid by the Company on September 30, 2003. Under the terms of the rights plan, the rights would become exercisable on the tenth day following the acquisition by a person or group of 15% or more of Gen-Probe's common stock, or commencement of a tender offer for Gen-Probe's common stock that would result in the ownership of 15% or more of the Company's common stock by one person or group. Each right will initially represent the right, under certain circumstances, to purchase 1/100 of a share of newly created Series A Junior Participating Preferred Stock of the Company at an exercise price of \$300. The exercise price is subject to adjustment by the Company. The Board of Directors may terminate the rights plan or redeem the rights at the redemption price of \$0.01 per right, subject to adjustment, at any time prior to the earlier of September 26, 2012, the expiration date of the rights, or the date of distribution of the rights, as determined under the rights plan. The rights plan has a term of 10 years. The initial distribution of rights is expected to be non-dilutive and non-taxable to stockholders for United States federal income tax purposes.

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

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

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

Notes to Consolidated Financial Statements (continued)

The Company adopted the 2000 Equity Participation Plan (the "2000 Plan") in August 2000 that provides for the issuance of up to 4,827,946 shares of common stock for grants under the 2000 Plan. The 2000 Plan provides for the grant of incentive and nonstatutory stock options. The exercise price of each option granted under the 2000 Plan must be equal to or greater than the fair market value of the Company's stock on the date of grant. The Board of Directors may determine the terms and vesting of all options; however, in no event will the contractual term exceed 10 years. Generally, options vest 25% or 33% one year from the grant date and 1/48 or 1/36, respectively, each month thereafter until the options are fully vested. All share amounts presented below for the 2000 Plan have been adjusted to reflect the reduction by approximately 17.6% for the contribution of cash and land to Gen-Probe through the merger of Gen-Probe Holding into Gen-Probe in July 2002.

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

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2001	3,604,116	\$ 13.36
Granted	1,618,998	12.12
Exercised	—	—
Cancelled	(545,022)	13.39
Outstanding at December 31, 2002	4,678,092	12.93
Granted	2,043,932	27.19
Exercised	(1,083,238)	13.20
Cancelled	(166,266)	16.34
Outstanding at December 31, 2003	5,472,520	18.10
Granted	2,061,329	37.21
Exercised	(1,178,052)	14.15
Cancelled	(351,743)	24.97
Outstanding at December 31, 2004	6,004,054	\$ 25.03

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

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Shares Exercisable	Weighted Average Exercise Price
\$ 6.75 – \$ 12.29	1,262,504	7.2	\$ 11.81	658,840	\$ 11.72
\$ 13.50 – \$ 15.51	1,211,828	6.0	13.70	1,040,870	13.67
\$ 19.19 – \$ 29.53	1,327,779	8.6	28.47	429,393	28.31
\$ 30.68 – \$ 36.47	564,198	9.0	33.87	49,297	32.26
\$ 36.59	1,196,000	9.6	36.59	—	—
\$ 37.42 – \$ 47.32	441,745	9.4	41.03	29,994	41.94
	6,004,054	8.1	\$ 25.03	2,208,394	\$ 16.73

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

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

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

Employee Stock Purchase Plan In May 2003, the Company adopted the ESPP that provides for the issuance of up to 1,000,000 shares of the Company's common stock, as adjusted to reflect the Stock Split. The ESPP is intended to qualify under Section 423 of the Internal Revenue Code and is for the benefit of qualifying employees as designated by the Board of Directors. Under the terms of the ESPP, purchases are made semiannually. Participating employees may elect to have a maximum of 15% of their compensation, up to a maximum of \$21,250 per calendar year, withheld through payroll deductions to purchase shares of common stock under the ESPP. The purchase price of the common stock purchased under the ESPP is equal to 85% of the fair market value of the common stock on the offering or "Grant Date" or the exercise or purchase date, whichever is lower. During the years ended December 31, 2004 and 2003, employees purchased 132,218 and 34,714 shares at an average price of \$28.49 and \$16.91 per share, respectively. As of December 31, 2004, 833,068 shares were reserved for future issuances under the ESPP.

9 COMMITMENTS AND CONTINGENCIES

Lease Commitments The Company leases certain facilities under operating leases which expire at various dates through February 2008.

Future minimum payments under operating leases as of December 31, 2004 are as follows (in thousands):

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

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

Collaborative Agreements Effective May 2, 1997, the Company entered into agreements which created a worldwide relationship between Gen-Probe and bioMérieux Vitek, Inc. ("bMx"). The collaboration involved research and development activities, as well as the transfer to bMx of product distribution rights in international markets, excluding Japan. As part of the agreements, Gen-Probe has licensed its probe-related technology to bMx to jointly develop probe assays and adapt and develop instrumentation during a five-year and ten-year term. In August 2000, the bMx agreement was amended to transition the relationship from a collaborative arrangement to a licensing agreement with certain performance obligations. In exchange for the royalties paid under the original agreement, Gen-Probe transferred all information and know-how to bMx as of December 31, 2000. Additionally, the Company transferred all products, work instructions, formulations and necessary materials needed for manufacturing key biochemistry components under the agreements to bMx by January 1, 2003, except that we continued to manufacture two enzyme formulations through July 15, 2003. Gen-Probe records revenue under this arrangement when specific milestones are achieved. Gen-Probe recognized milestone revenue of \$1,250,000 for the year ended December 31, 2002. In addition, the Company recognized \$1,870,000 in license fees related to this agreement for the year ended December 31, 2002. During the years ended December 31, 2004 and 2003, Gen-Probe recognized \$600,000 and \$750,000 in minimum annual royalties, respectively.

Notes to Consolidated Financial Statements (continued)

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

In July 1998, the Company entered into an agreement with Chiron Corporation ("Chiron") to form a strategic alliance to develop, manufacture and market nucleic acid probe assay systems for blood screening and certain areas of clinical diagnostics. Under the terms of the agreement, Chiron or a third party will market and sell products that utilize Chiron's intellectual property relating to hepatitis C virus ("HCV") and human immune deficiency virus Type 1 ("HIV-1") and the Company's patented technologies. The Company received an up-front license fee of \$10,000,000 from Chiron in 1998, which the Company recorded as deferred revenue and is being recognized as license revenue over a 10-year term. In September 1998, Chiron agreed to sell its diagnostic business to Bayer. As a result, the Company and Bayer have aligned under the terms of the agreement relating to clinical diagnostics. The Company recorded licensing revenues of approximately \$670,000

from Chiron for each of the years ended December 31, 2004, 2003 and 2002, respectively, related to this aspect of the agreement. In January 2004, the Company began United States clinical trials of the Procleix Ultrio assay on the fully automated, high-throughput TIGRIS instrument systems triggering a \$6,500,000 contract milestone payment under the agreement which the Company recorded as license revenue. The Company may receive an additional \$10,000,000 contract milestone payment upon Federal Drug Administration ("FDA") approval of the Procleix Ultrio assay.

In connection with its collaboration agreement with Chiron, the Company developed and supplied products to the American Red Cross, America's Blood Centers, American Independent Blood Centers, the United States military and others for pooled blood sampling under the terms of an Investigational New Drug ("IND"). The Company received monthly payments for costs that were incurred for development of the product. The contracts terminated upon commercial release of the product in the United States in 2002. Collaborative research revenue recorded under the terms of the agreements for the year ended December 31, 2002 was \$7,100,000. The Company does not separately track the costs applicable to the blood screening development collaboration with Chiron and therefore is not able to quantify the direct costs associated with the collaborative research revenue. The Company believes that the costs incurred related to the collaborative research revenue have exceeded the amounts recorded as revenue in all periods presented. In addition, for the years ended December 31, 2004 and 2003, the Company recognized \$18,543,000 and \$5,962,000 in collaborative research revenue through its collaboration with Chiron from deliveries of West Nile virus ("WNV") tests on a "cost recovery" basis. The Company expects to continue recognizing these sales as collaborative research revenue until such time as FDA approval has been received.

The Company is currently developing the Procleix Ultrio assay, a nucleic acid test ("NAT") assay to detect HIV-1, HCV and hepatitis B virus ("HBV"), in donated human blood. Gen-Probe develops these assays through its collaboration with Chiron. In March 2003, the Company signed a definitive written agreement with Chiron for

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

With respect to the Company's collaboration with Chiron, both parties have obligations to each other. The Company is obligated to manufacture and supply its blood screening assay to Chiron, and Chiron is obligated to purchase all of the quantities of this assay specified on a 90-day demand forecast, due 90 days prior to the date Chiron intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

In connection with the joint development of the Procleix HIV-1/HCV assay, and as a condition for Chiron's agreement to pay for most of the clinical trial costs related to approval of that assay, the Company agreed to pay the costs related to the clinical trial for the next joint development project with Chiron. The obligation of Gen-Probe was limited to the cost incurred for the previous joint clinical trial, which was approximately \$4,100,000. During the year ended December 31, 2004, the Company satisfied this obligation and began to bill Chiron for its share of qualifying clinical trial expenses for the eSAS Ultrio and WNV projects in accordance with their agreement.

Under the strategic alliance agreement the Company entered into with Chiron in June 1998, the Company has responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Chiron has responsibility for marketing, distribution and service of the blood screening products worldwide. During the first quarter of 2004, the Company recognized as royalty and license revenue, a \$6,500,000 milestone

payment, as the Company began clinical trial tests of the Procleix Ultrio assay on the TIGRIS instrument in the United States. Additional payments of up to \$10,000,000 are due to the Company in the future under the agreement if they achieve certain other specified milestones relating to the development of the TIGRIS instrument. There is no guarantee they will receive any additional milestone payments under this agreement.

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

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

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 \$653,000, \$569,000 and \$494,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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

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

In November 2003, the Company received \$4,300,000 of supplemental contract funding from the NIH. This contract extension supported the Company's pursuit of clinical studies and submission of a BLA, for our nucleic acid test for the detection of WNV in donated human blood. The Company initiated the development of this assay and has recognized collaborative research revenue under the contract extension as reimbursable costs were incurred. As of July 2004, the Company had billed and collected all monies under this contract.

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

ENZO BIOCHEM, INC. In June 1999, the Company was sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that the Company and other defendants, have willfully infringed United States patent no. 4,900,659, or the " '659 patent," through the manufacture and sale of products for the diagnosis of gonorrhoea. Enzo has asserted a damage claim based on a contention that Enzo was entitled to a reasonable royalty on all sales of Gen-Probe products for the detection of *Neisseria gonorrhoeae* bacteria from June 1993 through trial. Revenues from tests for the detection of *Neisseria gonorrhoeae* have constituted a significant portion of Gen-Probe's revenues during the relevant period. The Company believes that the claims of the '659 patent are invalid, unenforceable and may not be properly interpreted to cover its products. On July 27, 2004, the Court granted summary judgment in favor of the defendants and against Enzo, holding that the '659 patent is invalid based on the on-sale doctrine. Enzo has appealed the summary judgment to the United States Court of Appeals for the Federal Circuit. The parties have not yet completed their submissions of briefs to the Court of Appeals. The Company intends to vigorously defend the lawsuit. However, there can be no assurance that the case will be resolved in the Company's favor.

BAYER CORPORATION In November 2002, the Company filed a demand for arbitration against Bayer Corporation, or Bayer, in the Judicial Arbitration & Mediation Services, Inc., or JAMS, office in San Diego, California related to the Company's collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of HIV, hepatitis viruses and other specified viruses, subject to certain conditions. Gen-Probe's demand for arbitration stated that Bayer failed to fulfill the conditions required to maintain exclusive distribution rights. The arbitration demand seeks confirmation that the agreement grants Gen-Probe, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC has also been added as a respondent and counterclaimant. The hearing on the matter began on September 13, 2004 and closing arguments were completed on November 3, 2004. The arbitrator agreed to review additional written testimony following closing arguments, and has informed the parties that he intends to issue a written decision on or about March 25, 2005. There can be no assurances as to the final outcome of the arbitration.

On March 17, 2004, the Company filed a patent infringement action in the United States District Court for the Southern District of California against Bayer Corporation and Bayer Healthcare LLC, alleging that Bayer's bDNA nucleic acid tests for HIV and HCV infringe Gen-Probe's U.S. patent no. 5,955,261, entitled "Method for Detecting the Presence of Group-Specific Viral mRNA in a Sample." Bayer's bDNA tests are not covered by the collaboration agreement between the companies. Bayer has denied the allegations of infringement and alleged that the patent is invalid or unenforceable. No trial date has been set. There can be no assurances as to the final outcome of the litigation.

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

10 SIGNIFICANT CUSTOMERS AND GEOGRAPHIC INFORMATION

During the years ended December 31, 2004, 2003 and 2002, 47%, 42% and 30%, respectively, of net revenues were from one customer. No other customer accounted for more than 10% of revenues in any fiscal year.

During the years ended December 31, 2004, 2003 and 2002, 43%, 41% and 27%, respectively, of product sales were from the sale of commercially approved blood screening products. Other revenues related to the development of blood screening products prior to commercial approval are recorded in collaborative research revenue as disclosed in Note 9, Collaborative Agreements. During the years ended December 31, 2004, 2003 and 2002, 57%, 59% and 73%, respectively, of product sales were from the sale of clinical diagnostic products and instruments.

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

YEARS ENDED DECEMBER 31	2004	2003	2002
Total revenue:			
North America	\$ 224,607	\$ 180,924	\$ 132,355
Rest of World	45,100	26,267	23,242
	<u>\$ 269,707</u>	<u>\$ 207,191</u>	<u>\$ 155,597</u>

11 EMPLOYEE BENEFIT PLAN

Effective May 1, 1990, Gen-Probe established a Defined Contribution Plan (the "Plan") covering substantially all employees of Gen-Probe Incorporated beginning the month after they are hired. Employees may contribute up to 20% of their compensation per year (subject to a maximum limit imposed by federal tax law). Gen-Probe is obligated to make matching contributions each payroll equal to a maximum of 50% of the first 6% of compensation contributed by the employee. The contributions charged to operations related to Gen-Probe employees totaled \$1,332,000, \$1,110,000 and \$985,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Notes to Consolidated Financial Statements (continued)

12 QUARTERLY INFORMATION (UNAUDITED)

The following tables set forth the quarterly results of operations for each quarter within the two-year period ended December 31, 2004 (in thousands, except per share data). The information for each of these quarters is unaudited and has been prepared on the same basis as the Company's audited financial statements. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited quarterly results when read in conjunction with our audited financial statements and related notes. The operating results of any quarter are not necessarily indicative of results for any future period.

	Quarter Ended			
	March 31	June 30	September 30	December 31
2004				
Total revenues	\$ 76,486	\$ 61,225	\$ 63,487	\$ 68,509
Cost of product sales	13,864	13,164	15,272	17,608
Total operating expenses	46,378	43,114	46,544	51,173
Net income	19,728	11,761	11,110	11,976
Net income per share:				
Basic	\$ 0.40	\$ 0.24	\$ 0.22	\$ 0.24
Diluted	\$ 0.39	\$ 0.23	\$ 0.22	\$ 0.23
2003				
Total revenues	\$ 46,168	\$ 50,682	\$ 52,281	\$ 58,060
Cost of product sales	12,919	11,055	10,828	10,656
Total operating expenses	33,433	38,760	39,432	43,217
Net income	8,654	8,149	8,850	9,677
Net income per share:				
Basic	\$ 0.18	\$ 0.17	\$ 0.18	\$ 0.20
Diluted	\$ 0.18	\$ 0.17	\$ 0.18	\$ 0.19

Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been traded on the Nasdaq National Market since September 16, 2002 under the symbol GPRO. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sale prices for our common stock as reported on the Nasdaq National Market for the periods indicated. All share prices reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003.

2 0 0 3	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
2 0 0 4	High	Low
First Quarter	\$ 39.93	\$ 31.40
Second Quarter	\$ 47.61	\$ 32.80
Third Quarter	\$ 45.63	\$ 29.40
Fourth Quarter	\$ 47.10	\$ 31.52

As of March 1, 2005, there were approximately 7,639 stockholders of record of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

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*

Diana De Walt
*Vice President
Human Resources*

Martin B. Edelshain
*Vice President
Corporate Development*

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*



To accommodate future growth, Gen-Probe is constructing a new facility adjacent to its existing headquarters building in San Diego. The new facility will enable the Company to relocate employees currently located at leased locations back to one headquarters campus. At the construction site are executive committee members (front row from left): Niall Conway, Martin Edelshain, Hank Nordhoff, Jim Godsey, Larry Mimms and Bill Bowen; and (back row from left): Dan Kacian, Herm Rosenman, Diana De Walt and Glen Freiberg.

BOARD OF DIRECTORS

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

Raymond V. Dittamore
*Former Partner
 Ernst & Young LLP*

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

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

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*

**SCIENTIFIC
ADVISORY BOARD**

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

Michael Busch, MD, PhD
*Vice President of Research,
 Blood Systems Inc.; Director,
 Blood Systems Research Institute;
 Professor of Laboratory Medicine,
 University of California,
 San Francisco*

Daniel Farkas, PhD
*Director, Molecular Diagnostics,
 Department of Pathology, The
 Methodist Hospital, Houston,
 Texas and Associate Professor
 of Pathology and Laboratory
 Medicine, Weill Medical College
 of Cornell University*

Herbert A. Fritsche, PhD
*Professor and Chief of Clinical
 Chemistry, MD Anderson
 Cancer Center*

Ann Kessler, PhD
*Former Head of Global Project
 Management and Head of
 U.S. Exploratory Research,
 Hoffmann-La Roche*

Walter Stamm, MD
*Professor of Medicine and Head,
 Division of Allergy and Infectious
 Diseases, University of Washington*

Daniel Von Hoff, MD
*Director, Translational Drug
 Development, Translational
 Genomics Research Institute*

**STOCKHOLDER
INFORMATION**

HEADQUARTERS
 Gen-Probe Incorporated
 10210 Genetic Center Drive
 San Diego, California 92121
 www.gen-probe.com

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

INDEPENDENT AUDITORS
 Ernst & Young LLP
 501 West Broadway
 Suite 1100
 San Diego, California 92101

INDEPENDENT COUNSEL
 Cooley Godward LLP
 4401 Eastgate Mall
 San Diego, California 92121

TRANSFER AGENT
 Communications concerning
 transfer requirements, lost
 certificates and change of
 address should be directed to:

Mellon Investor Services
 Overpeck Centre
 85 Challenger Road
 1st Floor
 Ridgefield Park, New Jersey 07660
 Domestic: 800-903-1224
 International: 201-329-8728
 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 19, 2005, 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 March 23, 2005.

**REQUESTS FOR
 INFORMATION**
 Gen-Probe invites stockholders,
 securities 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: 858-410-8252
 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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 ULTRIO are trademarks of Chiron Corporation.

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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 "2004 Achievements," "2005 Goals," "Oncology," "HIV and Hepatitis C Virus," and "Hepatitis B Virus and West Nile Virus," 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 2005 growth targets, (ii) the possibility that the market for the sale of our new products, such as our APTIMA COMBO 2 Assay and TIGRIS 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 Proclex Ultrio and West Nile Virus Assays may not be commercially available in the time frames we anticipate, or at all, (v) we may not be able to compete effectively, (vi) we may not be able to maintain our current corporate collaborations and enter into new corporate collaborations, (vii) we are dependent on Chiron Corporation, Bayer Corporation and other third parties for the distribution of some of our products, (viii) we are dependent on a small number of customers, contract manufacturers and single source suppliers of raw materials, (ix) changes in third-party reimbursement policies regarding our products could adversely affect sales of our products, (x) changes in government regulation affecting our diagnostic products could harm our sales and increase our development costs, and (xi) 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 15, 2005, 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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