GEN PROBE INC
Form 10-Q
May 10, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

þ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2005

OR

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number 0-21872

GEN-PROBE INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**33-0044608**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
10210 Genetic Center Drive San Diego, CA	**92121**
(Address of Principal Executive Offices)	(Zip Code)

(858) 410-8000
(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes þ No o

As of April 29, 2005, there were 50,544,479 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

GEN-PROBE INCORPORATED

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GEN-PROBE INCORPORATED

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	March 31, 2005 (unaudited)	December 31, 2004
Current assets:		
Cash and cash equivalents	$ 32,332	$ 25,498
Short-term investments	180,498	168,328
Trade accounts receivable, net of allowance for doubtful accounts of $730 at March 31, 2005 and $664 at December 31, 2004, respectively	26,751	21,990
Accounts receivable other	475	3,136
Inventories	28,132	27,308
Deferred income taxes	8,188	7,725
Prepaid expenses	17,269	11,910
Other current assets	2,493	2,054
Total current assets	296,138	267,949
Property, plant and equipment, net	82,998	76,651
Capitalized software	22,837	23,466
Goodwill	18,621	18,621
Other assets	25,121	24,395
Total assets	$ 445,715	$ 411,082
Current liabilities:		
Accounts payable	12,694	6,729
Accrued salaries and employee benefits	11,659	11,912
Other accrued expenses	3,939	4,451
Income tax payable	4,021	1,188
Deferred revenue	11,930	9,467
Total current liabilities	44,243	33,747
Deferred income taxes	9,187	9,187
Deferred revenue	4,833	5,000
Deferred rent	299	309
Minority interest	1,776	1,810
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, $.0001 par value per share; 200,000,000 shares authorized, 50,442,131 and 50,035,490 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	5	5
Additional paid-in capital	260,198	248,767

Deferred compensation	(1,014)	(1,104)
Accumulated other comprehensive income	173	807
Retained earnings	126,015	112,554
Total stockholders equity	385,377	361,029
Total liabilities and stockholders equity	$ 445,715	$ 411,082

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Three Months Ended March 31,	
	2005 (unaudited)	**2004 (unaudited)**
Revenues:		
Product sales	$ 59,579	$ 55,030
Collaborative research revenue	6,344	6,731
Royalty and license revenue	2,905	14,725
Total revenues	68,828	76,486
Operating expenses:		
Cost of product sales	15,498	13,864
Research and development	18,683	18,419
Marketing and sales	7,426	6,812
General and administrative	7,191	7,283
Total operating expenses	48,798	46,378
Income from operations	20,030	30,108
Total other income, net	1,081	677
Income before income taxes	21,111	30,785
Income tax expense	7,650	11,057
Net income	$ 13,461	$ 19,728
Net income per share		
Basic	$ 0.27	$ 0.40
Diluted	$ 0.26	$ 0.39
Weighted average shares outstanding		
Basic	50,282	48,904
Diluted	52,367	50,998

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31,	
	2005 (unaudited)	**2004 (unaudited)**
Operating activities		
Net income	$ 13,461	$ 19,728
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	5,413	3,930
Stock compensation charges	125	109
Loss on disposal of property and equipment	39	9
Deferred rent	(10)	(6)
Stock option income tax benefits	4,692	1,585
Deferred revenue	2,296	(16)
Deferred income taxes	(465)	1,071
Minority interest	(58)	(47)
Changes in assets and liabilities:		
Accounts receivable	(2,070)	(7,778)
Inventories	(822)	(3,318)
Prepaid expenses	(5,359)	(2,526)
Other current assets	(439)	419
Accounts payable	5,963	1,605
Accrued salaries and employee benefits	(253)	(2,020)
Other accrued expenses	(525)	(8)
Income tax payable	2,827	8,135
Net cash provided by operating activities	24,815	20,872
Investing activities		
Proceeds from sales and maturities of short-term investments	20,790	34,311
Purchases of short-term investments	(32,900)	(45,544)
Purchases of property, plant and equipment	(10,228)	(4,509)
Capitalization of intangible assets	(1,643)	(345)
Other assets	(791)	(373)
Net cash used in investing activities	(24,772)	(16,460)
Financing activities		
Proceeds from issuance of common stock	6,705	5,358
Net cash provided by financing activities	6,705	5,358
Effect of exchange rate changes on cash and cash equivalents	86	692

Net increase in cash and cash equivalents	6,834	10,462
Cash and cash equivalents at the beginning of the period	25,498	35,973
Cash and cash equivalents at the end of the period	$ 32,332	$ 46,435
Supplemental disclosure of cash flow information:		
Cash paid for:		
Income taxes	$ 78	$ 658

See accompanying notes to consolidated financial statements.

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Notes to the Consolidated Financial Statements (unaudited)

Note 1 Basis of presentation

The accompanying interim consolidated financial statements of Gen-Probe Incorporated (Gen-Probe or the Company) at March 31, 2005, and for the three month periods ended March 31, 2005 and 2004, are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In management s opinion, the unaudited financial statements include all adjustments, consisting only of normal recurring accruals, necessary to state fairly the financial information therein, in accordance with generally accepted accounting principles. Interim results are not necessarily indicative of the results which may be reported for any other interim period or for the year ending December 31, 2005.

These unaudited consolidated financial statements and footnotes thereto should be read in conjunction with the audited financial statements and footnotes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2004.

Note 2 Reporting periods

The Company historically 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 2004 quarterly periods were deemed to end on March 31, June 30, September 30 and December 31. Beginning in 2005, coinciding with the Company s implementation of a new enterprise resource planning system, the Company s fiscal quarters now end on March 31, June 30, September 30 and December 31. The three months ended March 31, 2005 included one less business day compared to the same period in the prior year.

Note 3 Summary of significant accounting policies

Recent accounting pronouncement

In December 2004, the Financial Accounting Standards Board (FASB) issued revised Statement No. 123 (SFAS No. 123(R)) Share-Based Payment, which requires companies to expense the estimated fair value of all share-based payments to employees, including grants of employee stock options. Pro forma disclosure is no longer an alternative. In April 2005, the Securities and Exchange Commission (SEC) adopted a rule that will effectively require the Company to implement SFAS No. 123(R) beginning on January 1, 2006.

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 4 to the consolidated financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current standards. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. 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 for excess tax deductions were $4,692,000 and

$1,585,000 for the three month periods ended March 31, 2005 and 2004, respectively.

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales & Service, Inc., Gen-Probe Canada, Inc., Gen-Probe UK Limited (GPUK) 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.

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Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. These estimates include assessing the collectibility of accounts receivable, valuation of inventories and long-lived assets. Actual results could differ from those estimates.

Foreign currencies

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

Reclassifications

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

Note 4 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. For the three month periods ended March 31, 2005 and 2004, the following weighted average assumptions were used:

	Stock Option Plans		**ESPP**	
	2005	**2004**	**2005**	**2004**
Risk-free interest rate	3.59%	2.79%	2.60%	1.00%
Volatility	59%	67%	59%	59%
Dividend yield	0	0	0	0
Expected life (years)	4.0	4.0	0.5	0.5
Resulting average fair value	$ 23.60	$ 18.99	$ 7.63	$ 5.46

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 three month periods ended March 31, 2005 and 2004 was estimated on the date of grant using the Black-Scholes pricing model.

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

	Three Months Ended March 31,	
	2005	2004
Net income:		
As reported	$ 13,461	$ 19,728
Stock-based employee compensation expense included in reported net income, net of related tax effects	54	22
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(3,595)	(1,895)
Pro forma net income	$ 9,920	$ 17,855
Net income per share:		
As reported		
Basic	$ 0.27	$ 0.40
Diluted	$ 0.26	$ 0.39
Pro forma		
Basic	$ 0.20	$ 0.37
Diluted	$ 0.19	$ 0.35

The pro forma effects on net income for the three month periods ended March 31, 2005 and 2004 are not likely to be representative of the effects on reported net income in future years.

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.

Note 5 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):

	Three Months Ended March 31,	
	2005	**2004**
Net income	$ 13,461	$ 19,728
Weighted average shares outstanding Basic	50,282	48,904
Effect of dilutive common stock options outstanding	2,085	2,094
Weighted average shares outstanding Diluted	52,367	50,998
Net income per share:		
Basic	$ 0.27	$ 0.40
Diluted	$ 0.26	$ 0.39

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Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 127,500 and 145,470 shares for the three month periods ended March 31, 2005 and 2004, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Note 6 Comprehensive income

Comprehensive income is comprised of net income and other comprehensive income (loss), 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.

Components of comprehensive income, net of income taxes, were as follows (in thousands):

	Three Months Ended March 31,	
	2005	2004
Net income	$ 13,461	$ 19,728
Change in unrealized loss on investments	(825)	(196)
Foreign currency translation adjustment	190	916
Comprehensive income	$ 12,826	$ 20,448

Note 7 Intangible assets by asset class and related accumulated amortization

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

	March 31, 2005			December 31, 2004		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	$ 25,142	$ 2,305	$ 22,837	$ 25,142	$ 1,676	$ 23,466
Patents	15,348	14,235	1,113	15,305	14,062	1,243
Purchased intangible assets	33,636	32,078	1,558	33,636	31,994	1,642
License fees	23,626	1,410	22,216	22,026	752	21,274
Total	$ 97,752	$ 50,028	$ 47,724	$ 96,109	$ 48,484	$ 47,625
Goodwill	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621

In January 2005, the Company entered into a license agreement with Corixa Corporation (Corixa) and received the right to develop molecular diagnostic tests for 46 potential genetic markers in the areas of prostate, ovarian, cervical, kidney, lung and colon cancers. Pursuant to the terms of the agreement, the Company paid Corixa an initial access license fee of $1.6 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 the Company terminates the agreement prior to those dates. The initial

$1.6 million license fee has been recorded as an intangible asset which is being amortized on a straight-line basis to research and development expense over the life of the licensed patents.

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Note 8 Inventories

Net inventories are comprised of the following (in thousands):

	March 31, 2005	December 31, 2004
Raw materials and supplies	$ 5,410	$ 5,345
Work in process	13,226	10,429
Finished goods	9,496	11,534
	$ 28,132	$ 27,308

Note 9 Income taxes

The Company accounts for income taxes during interim periods in accordance with SFAS No. 109, Accounting for Income Taxes, APB No. 28, Interim Financial Reporting, and FIN 18, Accounting for Income Taxes in Interim Periods, an interpretation of APB Opinion No. 28. For interim reporting purposes, these rules require that a company determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a year-to-date basis.

The Company currently estimates its annual effective income tax rate to be approximately 36% for 2005, as compared to the actual 35.5% effective income tax rate in 2004. The Company expects that it will have sufficient taxable income after stock option related deductions to utilize the majority of its deferred tax assets.

Tax benefits of $4,692,000 and $1,585,000 in the three month periods ended March 31, 2005 and 2004, respectively, related to employee stock options and stock purchase plans were credited to stockholders equity.

Note 10 Stockholders equity

During the three month periods ended March 31, 2005 and 2004, options to purchase 405,895 and 295,529 shares of the Company s common stock were exercised by Gen-Probe employees at a weighted average exercise price of $16.52 and $12.87, respectively. The Company also issued 746 and 2,085 shares of common stock at fair market value during the three month periods ended March 31, 2005 and 2004, respectively, to members of the Board of Directors as partial consideration for services rendered. The Company recognized expense for these shares issued to the members of the Board of Directors during the three month periods ended March 31, 2005 and 2004, of $33,965 and $72,512, respectively, which was equal to the fair market value on the dates of issuance. Further, employees purchased 56,717 shares of the Company s common stock at an average price of $26.92 per share, during the three months ended March 31, 2004. There were no ESPP purchases during the three months ended March 31, 2005.

Changes in stockholders equity for the three months ended March 31, 2005 were as follows (in thousands):

Balance at December 31, 2004	$ 361,029
Net income	13,461
Other comprehensive income	(635)
Net proceeds from the issuance of common stock	6,705

Issuance of common stock to board members	34
Amortization of deferred compensation	91
Tax benefit from the exercise of stock options	4,692
Balance at March 31, 2005	$ 385,377

Note 11 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

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these matters were resolved in a manner unfavorable to the Company, its business, financial condition and results of operations would be harmed.

Enzo Biochem, Inc.

In June 1999, the Company was sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that the Company and other defendants have willfully infringed United States patent no. 4,900,659, or the 659 patent, through the manufacture and sale of products for the diagnosis of gonorrhea. Enzo has asserted a damage claim based on a contention that Enzo is entitled to a reasonable royalty on all sales of Gen-Probe products for the detection of *Neisseria gonorrhoeae* bacteria from June 1993 through trial. Revenues from tests for the detection of *Neisseria gonorrhoeae* have constituted a significant portion of Gen-Probe s revenues during the relevant period. The Company believes that the claims of the 659 patent are invalid, unenforceable and may not be properly interpreted to cover its products. On July 27, 2004, the Court granted summary judgment in favor of the Company and other defendants, and against Enzo, holding that the 659 patent is invalid based on the on-sale doctrine. Enzo has appealed the summary judgment to the United States Court of Appeals for the Federal Circuit. Oral argument of the appeal has been scheduled for June 7, 2005. 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 sought confirmation that the agreement grants Gen-Probe, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC was also added as a respondent and counterclaimant. The hearing on the matter began on September 13, 2004 and closing arguments were completed on November 3, 2004.

In April 2005, the Company received a tentative award in the arbitration. The arbitrator determined that the Company is entitled to a co-exclusive right to distribute qualitative Transcription-Mediated Amplification (TMA) assays to detect the hepatitis C virus and HIV-1. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as the Company requested. As a result of terminating the agreement, the Company will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Bayer also will be required to reimburse the Company $2.0 million for the Company s legal fees and expenses related to the arbitration proceedings.

The arbitrator rejected Bayer s multimillion-dollar counterclaim for damages. The tentative decision is subject to further proceedings before the arbitrator related to implementation of the award and Bayer has a right to appeal the final award to an arbitration appeal panel within JAMS. While the Company expects the tentative decision of the arbitrator to remain substantially unchanged upon entry of the final award, there can be no assurances as to the final outcome of the arbitration.

A separate patent infringement action that the Company filed in March 2004 against Bayer remains pending in the United States District Court for the Southern District of California. This action alleges that Bayer s bDNA nucleic acid tests for HIV and HCV infringe Gen-Probe s U.S. patent no. 5,955,261, entitled Method for Detecting the Presence of Group-Specific Viral mRNA in a Sample. 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.

Note 12 Commitment

In February 2005, the Company entered into a Supply and Purchase Agreement with F. Hoffman-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc. (Roche). Under this agreement, Roche will manufacture and supply DNA probes for human papillomavirus (HPV) to Gen-Probe. The Company will use these probes in molecular diagnostic assays. Pursuant to the agreement, the Company will pay Roche manufacturing fees of $20.0 million within 90 days of February 15, 2005 and $10.0

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million within 10 days of the occurrence of certain future commercial events. The Company also agreed to pay Roche transfer fees for the HPV products.

Item 2. ***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. We assume no obligation to update any forward-looking statements.

The following information should be read in conjunction with our March 31, 2005 consolidated financial statements and related notes thereto included elsewhere in this quarterly report and with our consolidated financial statements and notes thereto for the year ended December 31, 2004 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2004. We also urge you to review and consider our disclosures describing various risks that may affect our business, which are set forth under the heading Risk Factors in this report and in our Annual Report on Form 10-K for the year ended December 31, 2004.

Overview

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

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

Recent Events

Financial Results

During the three months ended March 31, 2005, we achieved strong financial results. Product sales for the current period were $59.6 million, compared to $55.0 million in the same period of the prior year, an increase of 8%. Net income for the current period was $13.5 million ($0.26 per diluted share), compared to $19.7 million ($0.39 per diluted share) in the same period of the prior year, a decrease of 33%. Total revenues for the current period were $68.8 million, compared to $76.5 million in the same period of the prior year, a decrease of 10%. The prior year period s net income and total revenues included a contract milestone of $6.5 million from Bayer (on behalf of 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 during the first quarter of last year.

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

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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 $3.0 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 46 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 recorded the initial $1.6 million license fee as an intangible asset which is being amortized on a straight-line basis to research and development expense over the underlying life of the patents. We also agreed to pay Corixa milestone payments totaling an additional $2.0 million on a product-by-product basis based on 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.

Supply Agreement

In February 2005, we entered into a Supply and Purchase Agreement with F. Hoffmann-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc., or Roche. Under this agreement, Roche will manufacture and supply DNA probes for human papillomavirus, or HPV to Gen-Probe. 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. Food and Drug Administration, or FDA, during the first quarter of 2005. Approximately 1200 infected units of blood have been intercepted by blood centers using our WNV assay under an Investigational New Drug, or IND, application 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.

Arbitration Award

In April 2005, we received a tentative award in our arbitration with Bayer HealthCare, LLC concerning the parties collaboration for the development and sale of nucleic acid diagnostic tests for viral organisms. The arbitrator determined that we are entitled to a co-exclusive right to distribute qualitative TMA assays to detect HCV and HIV-1. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as we requested. As a result of terminating the agreement, we will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Further, the arbitrator determined that Bayer will be required to reimburse us $2.0 million for our legal fees and expenses related to the arbitration proceedings. The tentative decision is subject to further proceedings and Bayer has a right to appeal the final award to an arbitration appeal panel. While we expect the tentative decision of the arbitrator to remain substantially unchanged upon entry of the final award, there can be no assurances as to the final outcome of the arbitration (See Note 11).

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 collaborative research and development activities and for the products we provide Chiron prior to regulatory approval. Our royalty and license revenues reflect fees paid to us by third parties for the use of our proprietary technology. For the three months ended March 31, 2005, product sales, collaborative research revenues and royalty and license revenues equaled 87%, 9% and 4%, respectively, of our total revenues of $68.8 million. For the same

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period in the prior year, product sales, collaborative research revenues, and royalty and license revenues equaled 72%, 9%, and 19%, respectively, of our total revenues of $76.5 million.

Product sales

Our primary source of revenue is the sale of clinical diagnostic and blood screening products in the United States. Our clinical diagnostic products include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During the first quarter of 2005, we shipped approximately 5.4 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 the contractual transfer prices specified in our collaboration agreement with Chiron for sales to blood bank facilities located in countries where our products have obtained governmental approvals. Blood screening product sales are then adjusted monthly corresponding to Chiron s payment to us of amounts reflecting our ultimate share of net revenue from sales by Chiron to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Chiron to third-parties, less freight, duty and certain other adjustments specified in our agreement with Chiron, multiplied by our share of the net revenue. Our share of the net revenue was 43.0% with respect to sales of assays that include a test for HCV beginning the second quarter of 2002 (following FDA approval in February 2002) upon implementation of commercial pricing, through April 6, 2003, after which our share of net revenues from sales of assays that include a test for HCV was adjusted to 47.5%. Effective January 1, 2004, our share of net revenues from commercial sales of assays that include a test for HCV was permanently changed to 45.75% under our agreement with Chiron. With respect to commercial sales of blood screening assays under our collaboration with Chiron that do not include a test for HCV, such as possible future commercial tests for WNV, we will 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. For both of the three month periods ended March 31, 2005 and 2004, we recognized $4.5 million, 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 IND. For the three months ended March 31 2005, we recognized $0.7 million in reimbursements for expenses incurred for WNV. There were no reimbursements for WNV during the same period in the prior year. 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. For each of the three month periods ended March 31, 2005 and 2004, we recognized $0.5 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.

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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.

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 the three month periods ended March 31, 2005 and 2004, our manufacturing facilities produced development lots for WNV and Procleix Ultrio assays. The majority of costs associated with these development lots are classified as research and development expense. The portion of a development lot that is manufactured for commercial sale outside the United States is 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, are classified as research and development expense prior to FDA approval.

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 additional costs associated with the manufacture of

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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 there have been no significant changes during the three months ended March 31, 2005 to the items that we disclosed as our critical accounting policies and estimates in Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2004, except for the item discussed below.

Future Accounting Requirements

In December 2004, the Financial Accounting Standards Board, FASB, issued revised Statement 123, or SFAS No. 123(R), Share-Based Payment, which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced that the accounting provisions of SFAS No. 123(R) will be effective for the first quarter of 2006. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in SFAS No. 123(R) will be applied to valuing stock-based awards granted after the effective date and the impact that the recognition of compensation expense related to such awards will have on our financial statements.

Results of Operations

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

	Three Months Ended March 31,	
	2005	**2004**
Total revenues	100%	100%
Product sales	87%	72%
Collaborative research revenue	9%	9%
Royalty and license revenue	4%	19%
Operating expenses:		
Cost of product sales	23%	18%
Research and development	27%	24%
Marketing and sales	11%	9%
General and administrative	10%	10%

Total operating expenses	71%	61%
Income from operations	29%	39%
Total other income, net	2%	1%
Income before income taxes	31%	40%
Income tax expense	11%	14%
Net income	20%	26%

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	Three Months Ended March 31,		Change	
	2005	2004	Amount	%
	(In millions, except per share data)			
Statement of income:				
Revenues:				
Product sales	$ 59.6	$ 55.0	$ 4.6	8%
Collaborative research revenue	6.3	6.8	(0.5)	(7%)
Royalty and license revenue	2.9	14.7	(11.8)	(80%)
Total revenues	68.8	76.5	(7.7)	(10%)
Operating expenses:				
Cost of product sales	15.5	13.9	1.6	12%
Research and development	18.7	18.4	0.3	2%
Marketing and sales	7.4	6.8	0.6	9%
General and administrative	7.2	7.3	(0.1)	(1%)
Total operating expenses	48.8	46.4	2.4	5%
Income from operations	20.0	30.1	(10.1)	(34%)
Net income	$ 13.4	$ 19.7	$ (6.3)	(32%)
Net income per share				
Basic	$ 0.27	$ 0.40	$ (0.13)	(33%)
Diluted	$ 0.26	$ 0.39	$ (0.13)	(33%)
Weighted average shares outstanding				
Basic	50.3	48.9		
Diluted	52.4	51.0		

Amounts and percentages in this table and throughout our discussion and analysis of financial conditions and results of operations may reflect rounding adjustments.

Three Months Ended March 31, 2005 Compared to Three Months Ended March 31, 2004
(Percentages have been rounded to the nearest whole percentage)

Product sales

The $4.6 million, or 8%, increase in product sales was principally the result of a $5.0 million increase in sales of our APTIMA Combo 2 assay along with a $2.2 million increase in worldwide commercial sales of our blood screening products, both in the United States and international markets, partially offset by a $2.4 million decrease in PACE product sales. Blood screening product sales of $25.4 million, increased by 9% and represented 43% of product sales, for the three months ended March 31, 2005, compared to $23.2 million, or 42% of product sales, for the three months ended March 31, 2004. The increase in blood screening sales in 2005 was due principally to increased international sales in 2005 of our Procleix Ultrio assay, partially offset by a decrease in January 2004 in our share of net revenues from Chiron (from 47.5% to 45.75%).

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 by others of competing products into both the STD and blood screening

markets and continuing pricing pressure as it relates to the STD market.

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Collaborative research revenue

The $0.5 million, or 7%, decrease in collaborative research revenue was primarily the result of a $1.6 million decrease due to completion of NIH funding of our WNV assay development work during 2004, partially offset by a $0.7 million increase in revenue for reimbursement from Chiron for WNV development costs.

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

The $11.8 million, or 80%, decrease in royalty and license revenue 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, effective in the first quarter of 2004. These decreases were partially offset by $1.9 million in license fee revenue recognized from bioMérieux in January 2005, which was based on the total number of targets that may be selected pursuant to the terms of the September 2004 agreement between Gen-Probe and bioMerieux.

Royalty and license revenue may fluctuate based on the nature of the related agreements and the timing of receipt of license fees. Results in any one period are not necessarily indicative of results to be achieved in the future. In addition, our ability to generate additional royalty and license revenue 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

The $1.6 million, or 12%, increase in cost of sales was principally attributed to the volume increase in product sales and the amortization of capitalized software development costs related to our TIGRIS instrument. Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales are also affected by manufacturing efficiencies, allowances for scrap or expired materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

Our gross profit margin on product sales decreased to 74% in the three months ended March 31, 2005 from 75% in the same period of the prior year. The gross profit margin decrease was primarily attributed to the amortization of capitalized software development costs of $0.6 million, which began in the second quarter of 2004, and the increase in sales of TIGRIS instruments, which have a lower margin.

We anticipate that requirements for smaller pool sizes or ultimately individual donor testing of blood samples, if and when implemented, could result in lower gross margin rates, as additional tests would be required to deliver the sample results, unless corresponding increase in sales pricing structure is implemented. We are not able to accurately predict the timing and 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 were 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. The $0.3 million, or 2%, increase in R&D spending was due to a $2.6 million increase in expenses resulting from higher staffing levels to support

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product development projects, partially offset by a $1.0 million decrease in development lot production and lower per unit costs, along with a $1.2 million decrease in expenses related to clinical trials for blood screening products.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. The $0.6 million, or 9%, increase in spending principally included a $0.7 million increase in salaries, benefits, commissions and other personnel related costs in our marketing, sales, and technical service organization to support APTIMA Combo 2 market expansion and TIGRIS instrument commercialization, partially offset by a $0.2 million decrease in professional fees due to non-recurring consultant fees.

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. The $0.1 million, or 1%, decrease in spending was the result of a $0.8 million decrease in professional fees as the costs associated with the Bayer arbitration have decreased, partially offset by an increase in salaries, benefits and other expenses resulting from higher staffing levels.

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 $0.4 million net increase in other income was primarily due to an increase in interest income resulting from an increase in the average balance of our short-term investments.

Income tax expense

Income tax expense decreased to $7.7 million, or 36.2% of pretax income, in the three months ended March 31, 2005, from $11.1 million, or 35.9% of pretax income, in the same period of the prior year. The slight increase in our effective tax rate in 2005 was principally attributed to an increase in the amount of pre-tax income taxed at the highest marginal tax rate. Further, the level of 2005 R&D tax credits is expected to be proportionately lower than the increase in pre-tax income.

Liquidity and capital resources
(In thousands)

	March 31, 2005	December 31, 2004
Cash, cash equivalents and short-term investments	$ 212,830	$ 193,826
Working capital	251,895	234,202

	Three Months Ended March 31,	
	2005	2004
Cash provided by (used in):		
Operating activities	$ 24,815	$ 20,872
Investing activities	(24,772)	(16,460)
Financing activities	6,705	5,358

Purchases of property, plant and equipment (included in investing activities above)	(10,228)	(4,509)

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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 March 31, 2005, we had $212.8 million of cash and cash equivalents and short-term investments.

The $3.9 million increase in net cash provided by operating activities during the three months ended March 31, 2005 was primarily the result of a $6.0 million increase in accounts payable and a $4.7 million increase in stock option income tax benefits, partially offset by a $5.4 million increase in prepaid expenses. The increase in prepaid expenses during the three months ended March 31, 2005 was due to the timing of payments to one of our vendors for the manufacture of TIGRIS instruments.

The $8.3 million increase in our investing activities during the three months ended March 31, 2005 included a $5.7 million increase in our capital expenditures (primarily related to the construction of our new building) and a $1.6 million payment to Corixa for a license fee. 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 $1.3 million increase in net cash provided by financing activities during the three months ended March 31, 2005 was attributed to a $2.8 million increase in proceeds from the exercise of stock options, partially offset by a $1.5 million decrease in employee purchases of our common stock made through our Employee Stock Purchase Plan, or ESPP. During 2004, for administrative reasons, we changed the purchase dates of our offering periods to occur at the end of June and December. As a result, no purchases occurred during the current quarter. 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 2006, 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 March 31, 2005, we were in compliance with all covenants.

In July 2004, we commenced construction of an additional building to expand our main San Diego campus. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 190,000 square feet built-out with interior improvements. The additional space that will not initially be built-out will allow for future expansion. The first phase of this project is currently estimated to cost approximately $44.0 million, of which $12.8 million was capitalized to construction in-progress as of March 31, 2005. These costs are being capitalized as incurred and depreciation will commence upon our completion and use, which is planned for early 2006.

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 our ERP system.

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

Contractual obligations and commercial commitments

Our significant 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 46 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.

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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 purchase 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 agreed to pay $10.0 million upon achievement of certain commercial events. Further, we have agreed to pay Roche transfer fees for the HPV products.

Additionally, the Company is obligated to purchase raw materials used in manufacturing and instrumentation from two key vendors during 2005. The minimum purchase commitment is approximately $6.2 million as of March 31, 2005.

Our supply commitments include:

Chiron. 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 determined on a rolling 12-month forecast.

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

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 additional equity or 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.

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.

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Summary of Option Activity
(Shares in thousands)

	Shares Remaining Available for Future Issuance	Options Outstanding Number of Shares to be Issued Upon Exercise	Weighted Average Exercise Price
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
December 31, 2004	1,915	6,004	$ 25.03
Grants	(143)	143	48.85
Exercises		(406)	16.52
Cancellations	90	(90)	32.79
March 31, 2005	1,862	5,651	$ 25.94

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

	Exercisable		Unexercisable		Total	
As of March 31, 2005	**Shares**	**Wtd. Avg. Exercise Price**	**Shares**	**Wtd. Avg. Exercise Price**	**Shares**	**Wtd. Avg. Exercise Price**
In-the-Money	2,131	$ 17.72	3,339	$ 30.27	5,470	$ 25.38
Out-of-the-Money[(1)]			181	48.53	181	48.53
Total Options Outstanding	2,131		3,520		5,651	

(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, $44.56, at the close of business on March 31, 2005.

Risk Factors

The following information sets forth facts that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time.

Our quarterly revenue and operating results may vary significantly in future periods and our stock price may decline.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenues are unpredictable and may fluctuate due to changes in demand for our products, the timing of the execution of customer contracts and the initiation or termination of corporate collaboration agreements. A significant portion of our costs also can vary substantially between quarterly or annual reporting periods. For example, the total amount of research and development costs in a period often depends on the amount of research and development costs we incur in connection with manufacturing developmental lots and clinical trial lots. We incurred substantial costs of manufacturing these lots in 2004 and will continue to incur expense in 2005 and beyond. Moreover, a variety of factors may affect our ability to make accurate forecasts regarding our operating results. For example, our blood screening products and some of our clinical diagnostic products, such as APTIMA Combo 2, have a relatively limited sales history, which limits our ability to project future sales accurately. Our share of revenue under our blood screening collaboration with Chiron, from commercial sales of assays that test for HCV, decreased to 45.75% of net revenues as of January 1, 2004, as a result of the amendment to our collaboration agreement with Chiron. In addition, we base our internal projections of our international sales on projections prepared by our distributors of these products, therefore we are dependent upon the accuracy of those projections. Because of all of these factors, our

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operating results in one or more future quarters may fail to meet or exceed financial guidance we may provide from time to time and the expectations of securities analysts or investors, which could cause our stock price to decline. In addition, the trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about our business and that of our competitors.

We are dependent on Chiron and other third parties for the distribution of some of our products. If any of our distributors terminates its relationship with us or fails to adequately perform, our product sales will suffer.

We rely on Chiron to distribute our blood screening products and Bayer to distribute some of our viral clinical diagnostic products. Commercial product sales by Chiron accounted for 37% of our total revenues for the three months ended March 31, 2005 and 35% of our total revenues for 2004. Our agreement with Chiron will terminate in 2010 unless extended by the development of new products under the agreement, in which case the agreement will expire upon the later of the end of the original term or five years after the first commercial sale of the last new product developed during the original term.

In February 2001, we commenced an arbitration proceeding against Chiron in connection with our blood screening collaboration. The arbitration related primarily to the propriety of various deductions from gross revenues made by Chiron prior to calculating Gen-Probe s share of revenues and the parties respective shares of revenues received from The American Red Cross prior to FDA approval of the Procleix HIV-1/HCV blood screening assay. Other disputed items included the parties respective obligations in connection with clinical trials of the Procleix HIV-1/HCV blood screening assay and future assays, Chiron s obligation to purchase blood screening assays in compliance with its forecasts and the parties respective obligations with respect to royalties to be paid on a patent license from a third party. By December 2001, we negotiated a resolution to most of the disputed items, and in January 2002, we received $6.9 million in partial settlement of the claims. In the event that we or Chiron commence arbitration against each other in the future under the collaboration agreement, proceedings could delay or decrease our receipt of revenue from Chiron or otherwise disrupt our collaboration with Chiron, which could cause our revenues to decrease and our stock price to decline.

Our agreement with Bayer for the distribution of our products will terminate in 2010. In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by us for the detection of HIV, hepatitis virus and other specified viruses, subject to specific conditions. Our demand for arbitration stated that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. Accordingly, we sought confirmation that the agreement grants us, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC was also added as a respondent and counterclaimant. The hearing on the matter began on September 13, 2004 and closing arguments were completed on November 3, 2004. In April 2005, we received a tentative award in the arbitration. The arbitrator determined that the were are entitled to a co-exclusive right to distribute qualitative Transcription-Mediated Amplification, or TMA, assays to detect HCV and HIV-1. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as we requested. As a result of terminating the agreement, we will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Bayer also will be required to reimburse us $2 million for our legal fees and expenses related to the arbitration proceedings. The arbitrator rejected Bayer s multimillion-dollar counterclaim for damages. The tentative decision is subject to further proceedings before the arbitrator related to implementation of the award and Bayer has a right to appeal the final award to an arbitration appeal panel within JAMS.

We rely upon bioMérieux for distribution of some of our products in most of Europe, Rebio Gen, Inc. for distribution of some of our products in Japan and various independent distributors for distribution of our products in other regions. Our distribution agreement with bioMérieux terminates on May 1, 2006, although it may terminate earlier under certain circumstances. The distribution rights revert back to Gen-Probe upon termination. Our distribution agreement with Rebio Gen terminates on December 31, 2005.

If any of our distribution or marketing agreements is terminated, particularly our agreement with Chiron, and we are unable to renew or enter into an alternative agreement or if we elect to distribute new products directly, we would have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to market successfully our products, our product sales would decrease.

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

We rely, to a significant extent, on our corporate collaborators for the joint development and marketing of our products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner, the pre-clinical or clinical development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. We cannot control the amount and timing of resources our corporate collaborators devote to our programs or potential products. In addition, we expect to rely on our corporate collaborators for the commercialization of some of our products.

The continuation of any of our collaboration agreements depends on their periodic renewal by us and our collaborators. Our agreement with Chiron will terminate in 2010 unless extended by the development of new products under the agreement, in which case it will expire upon the later of the original term or five years after the first commercial sale of the last new product developed during the original term. Subject to the final outcome of our arbitration with Bayer, the remaining provisions of our Bayer collaboration agreement will terminate in 2010. Both collaboration agreements are also subject to termination prior to expiration upon a material breach by either party to the agreement.

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

If our TIGRIS instrument reliability does not meet market expectations, we may be unable to retain our existing customers and attract new customers.

Complex diagnostic instruments such as our TIGRIS instrument usually require operating and reliability improvements following their initial introduction. We believe that our experience with our TIGRIS instrument, now in its early introduction stage, is consistent with the general experience for comparable diagnostic instruments. We have initiated an in-service reliability improvement program for our TIGRIS instrument and a number of improvements already have been installed at customers sites. If the continuous improvement program does not result in improved instrument reliability, we could incur greater than anticipated service expenses and market acceptance of the instrument could be adversely affected. Additionally, failure to resolve reliability issues as they develop could materially damage our reputation and prevent us from retaining our existing customers and attracting new customers.

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

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

In the markets for clinical diagnostic products, a number of competitors, including F. Hoffmann-La Roche Ltd. and its subsidiary, Roche Molecular Diagnostics, Inc., Abbott Laboratories, Becton Dickinson and Company and bioMérieux S.A., compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. In markets outside of the United States, other factors, including local distribution systems, complex regulatory environments and differing medical philosophies and product preferences, influence competition as well. Some of our competitors have, and in the future these and other competitors may have, significantly greater financial, marketing, sales, manufacturing, distribution and technological resources than us. Moreover, these companies may have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do. In addition, we have licensed some of our proprietary technology relating to certain clinical diagnostic and food pathogen applications for use on specific instruments to bioMérieux, and we may license other technologies to potential

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competitors in the future. As a result, we may in the future compete with bioMérieux and these other licensees for sales of products incorporating our technology. Our competitors may be in a stronger position to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners than we are. We believe that our competitors are developing real time or kinetic nucleic acid assays and are developing semi-automated instrument systems to perform real time assays. Our competitors may be further in the development process than we are with respect to such assays and instrumentation.

In the market for blood screening products, our primary competitor is Roche Molecular Systems, Inc. which received FDA approval of its Polymerase Chain Reaction, or PCR, based NAT tests for blood screening in December 2002 and with whom we recently entered into a supply and purchase agreement. We also compete with assays developed internally by blood banks and laboratories based on PCR technology, an HCV antigen assay marketed by Ortho Clinical Diagnostics, a subsidiary of Johnson & Johnson, and immunoassay products from Abbott Laboratories. In the future, our blood screening products also may compete with viral inactivation technologies and blood substitutes.

Chiron, with whom we have a collaboration agreement for our blood screening products, retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening. Chiron has granted HIV and HCV licenses to Roche Molecular Systems in the blood screening and clinical diagnostics fields. Chiron has granted HIV and HCV licenses in the clinical diagnostic field to Bayer Healthcare LLC, which also has the right to grant certain additional HIV and HCV sublicenses in the field to third parties. Chiron has granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux). To the extent that Chiron grants additional licenses in blood screening or Bayer grants additional licenses in clinical diagnostics, further competition will be created for sales of HCV and HIV assays and these licenses could affect the prices that can be charged for our products.

Our profit margin on the sale of blood screening assays may decrease upon the implementation of individual donor testing.

We currently receive revenues from the sale of the Procleix HIV-1/HCV blood screening assay for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test, however, Chiron sells our Procleix HIV-1/HCV assay to blood collection centers on a per donation basis. We expect the blood screening market ultimately to transition from pooled testing to individual donor testing. A greater number of tests will be required for individual donor testing than are now required for pooled testing. Under our collaboration agreement with Chiron, we bear the cost of manufacturing our Procleix HIV-1/HCV assay. The greater number of tests required for individual donor testing will increase our variable manufacturing costs, including costs of raw materials and labor. If the price per donor or total sales volume does not increase in line with the increase in our total variable manufacturing costs, our gross profit margins from sales of the blood screening assay may decrease upon the adoption of individual donor testing. We are not able to predict accurately the extent to which our gross profit margin may be negatively affected as a result of individual donor testing, because we do not know the ultimate selling price that Chiron would charge to the end user if individual donor testing were implemented.

Because we depend on a small number of customers for a significant portion of our total revenues, the loss of any of these customers or any cancellation or delay of a large purchase by any of these customers could significantly reduce our revenues.

Historically, a limited number of customers has accounted for a significant portion of our total revenues, and we do not have any long-term commitments with these customers other than our collaboration agreement with Chiron. Our blood screening collaboration with Chiron accounted for 47% of our total revenues for the three months ended March 31, 2005 and for the year ended December 31, 2004. Our blood screening collaboration with Chiron is largely

dependent on two large customers in the United States, The American Red Cross and America s Blood Centers, although we did not receive any revenues directly from those entities. Chiron was our only customer that accounted for greater than 10% of our total revenues for the three months ended March 31, 2005. In addition, Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings and various state and city public health agencies accounted for an aggregate of 22% of our total revenues for the three months ended March 31, 2005 and 20% of our total revenues for 2004. Although state and city public health agencies are legally independent of each other, they tend to act similarly with respect to their product purchasing decisions. We anticipate that our operating results will continue to depend to a significant extent upon revenues from a small number of customers. The loss of any of our key customers, or a significant reduction in sales to those customers, could significantly reduce our revenues.

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Intellectual property rights on which we rely to protect the technologies underlying our products may be inadequate to prevent third parties from using our technologies or developing competing products.

Our success will depend in part on our ability to obtain patent protection for, or maintain the secrecy of, our proprietary products, processes and other technologies for development of blood screening and clinical diagnostic products and instruments. Although we have 201 United States patents and 188 foreign patents, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by September 28, 2021, and the patents we may obtain in the future also will expire over time.

The scope of any of our issued patents may not be broad enough to offer meaningful protection. In addition, others may challenge our current patents or patents we may obtain in the future and, as a result, these patents could be narrowed, invalidated or rendered unenforceable, or we may be forced to stop using the technology covered by these patents or to license technology from third parties. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the United States. Any patents issued to us or our strategic partners may not provide us with any competitive advantages, and the patents held by other parties may limit our freedom to conduct our business or use our technologies. Our efforts to enforce and maintain our intellectual property rights may not be successful and may result in substantial costs and diversion of management time. Even if our rights are valid, enforceable and broad in scope, competitors may develop products based on technology that is not covered by our patents.

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

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

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. Because we produce and provide many different products and services in this industry, we have faced in the past, are currently facing, and may face in the future, patent infringement suits by companies that control patents for products and services similar to ours or other suits alleging infringement of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against

third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management s attention from other business concerns. The cost of this litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

Recently, we have been involved in a number of patent disputes with third parties, a number of which remain unresolved. For example, we are in litigation with Enzo Biochem Inc. which claims that genetic sequences used in certain of our gonorrhea testing products infringe one of its patents. In February 2005, we received a letter from the Institut Pasteur regarding alleged infringement of Institut Pasteur s European Patent EP 0 178 978 (Cloned DNA sequences, hybridizable

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with genomic RNA of lymphadenopathy-associated virus, or LAV, (978 patent) by the HIV-1 nucleic acid screening assays performed on our Procleix system that is marketed and distributed by Chiron. There can be no assurances as to the ultimate outcomes of these matters.

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

While there is a federal preemption defense against product liability claims for medical products that receive premarket approval from the FDA, we believe that no such defense is available for our products that we market under a 510(k) clearance. As such, we are subject to potential product liability claims as a result of the design, development, manufacture and marketing of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates. In addition, we would have to pay any amount awarded by a court in excess of our policy limits. Our insurance policies have various exclusions, and thus we may be subject to a product liability claim for which we have no insurance coverage, in which case, we may have to pay the entire amount of any award. In addition, insurance varies in cost and can be difficult to obtain, and we may not be able to obtain insurance in the future on terms acceptable to us, or at all. A successful product liability claim brought against us in excess of our insurance coverage, may require us to pay substantial amounts, which could harm our business and results of operations.

We are exposed to risks associated with acquisitions and other long-lived and intangible assets that may become impaired and result in an impairment charge.

As of March 31, 2005, we had approximately $149.6 million of long-lived assets, including $22.8 million of capitalized software relating to our TIGRIS instrument, goodwill of $18.6 million and $24.9 million of capitalized license fees, patents and purchased intangibles that have been included in Other assets on the face of the balance sheet. Additionally, we had $34.9 million of land and building, $5.4 million of leasehold improvements, $14.6 million of construction in-progress and $28.1 of equipment and furniture and fixtures. The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. Such events or changes might include a significant decline in market share, a significant decline in profits, rapid changes in technology, significant litigation or other matters. Adverse events or changes in circumstances may affect the estimated undiscounted future operating cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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

The market for our products is characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products, such as our NAT assay to detect WNV. For example, we believe that we will need to continue to provide new products that can detect a greater number of organisms from a single sample. We also believe that we must develop new assays that can be performed on automated instrument platforms, such as our TIGRIS instrument.

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends, as well as precise technological execution. In addition, the successful

development of new products will depend on the development of new technologies. We will be required to undertake time-consuming and costly development activities and to seek regulatory approval for these new products. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of these new products. Regulatory clearance or approval of any new products may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and the new products may not be successfully commercialized.

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

In recent years, we have incurred significant costs in connection with the development of our blood screening products and our TIGRIS instrument. We expect our expense levels to remain high in connection with our research and development as we continue to expand our product offerings and continue to develop products and technologies in collaboration with our strategic partners. As a result, we will need to continue to generate significant revenues to maintain profitability. Although we expect our research and development expenses as a percentage of revenue to decrease in future periods, we may not be able to generate revenues and may not maintain profitability in the future. Our failure to maintain profitability in the future would cause the market price of our common stock to decline.

We may not have financing for future capital requirements, which may prevent us from addressing gaps in our product offerings or improving our technology.

Although historically our cash flow from operations has been sufficient to satisfy working capital, capital expenditure and research and development requirements, in the future we may need to incur additional debt or issue equity in order to fund these requirements as well as to make acquisitions and other investments. If we cannot obtain additional debt or equity financing on acceptable terms or are limited with respect to incurring additional debt or issuing equity, we may be unable to address gaps in our product offerings or improve our technology, particularly through strategic acquisitions or investments.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including but not limited to the following:

for research and development to successfully develop our new technologies and products,

to conduct clinical trials,

to obtain regulatory approval for new products,

to file and prosecute patent applications and defend and assert patents to protect our technologies,

to manufacture additional products ourselves or through third parties,

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

to acquire new technologies, products or companies.

If we raise funds through the issuance of debt or equity, including without limitation through the issuance of equity or debt securities pursuant to our Form S-3 shelf registration statement that we filed on August 29, 2003 with the Securities and Exchange Commission relating to the possible future sale of up to an aggregate of $150 million of debt or equity securities, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation and may contain other provisions that adversely effect the rights of the holders of our common stock. The terms of the debt securities may impose restrictions on our operations. If we raise funds through the issuance of equity or debt convertible into equity, this issuance would dilute your ownership interest in us.

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

We have only one third-party manufacturer for each of our instrument product lines, which exposes us to increased risks associated with delivery schedules, manufacturing capability, quality assurance, quality and costs.

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is the only manufacturer of our TIGRIS instrument. MGM Instruments, Inc. is the only manufacturer of our LEADER series of luminometers. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have no firm long-term commitments from KMC Systems, MGM Instruments or any of our other manufacturers to supply products to us for any specific period, or

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in any specific quantity, except as may be provided in a particular purchase order. If KMC Systems, MGM Instruments or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its manufacturing operations or becomes insolvent, then product shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation.

Further, our business would be harmed if we fail to manage effectively the manufacturing of our products. Because we place orders with our manufacturers based on our forecasts of expected demand for our products, if we inaccurately forecast demand, we may be unable to obtain adequate manufacturing capacity or adequate quantities of components to meet our customers delivery requirements, or we may accumulate excess inventories.

We may in the future need to find new contract manufacturers to increase our volumes or to reduce our costs. We may not be able to find contract manufacturers that meet our needs, and even if we do, qualifying a new contract manufacturer and commencing volume production is expensive and time consuming. For example, qualifying a new manufacturer of our TIGRIS instrument would take approximately 12 months. If we are required or elect to change contract manufacturers, we may lose revenues, and our customer relationships may suffer.

If we or our contract manufacturers are unable to manufacture our products in compliance with regulatory requirements, in sufficient quantities, on a timely basis and at acceptable costs, our ability to sell our products will be harmed.

We must manufacture our products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. Significant additional work will be required for scaling-up manufacturing of each new product prior to commercialization, and we may not successfully complete this work. Manufacturing and quality control problems have arisen and may arise as we attempt to scale-up our manufacturing of a new product, and we may not achieve scale-up in a timely manner or at a commercially reasonable cost, or at all. In addition, although we expect some of our newer products and products under development to share production attributes with our existing products, production of these newer products may require the development of new manufacturing technologies and expertise.

In addition, the amplified NAT tests that we are producing are significantly more expensive to manufacture than our non-amplified products. As we continue to develop new amplified NAT tests in response to market demands for greater sensitivity, our product costs will increase significantly. We sell our products in a number of cost-sensitive market segments, and we may not be able to manufacture these more complex amplified tests at costs that would allow us to maintain our historical gross margins. In addition, new products that detect more than one target organism will contain significantly more complex reagents, which will increase the cost of our manufacturing processes and quality control testing. We or other parties we engage to help us may not be able to manufacture these products at a cost or in quantities that would make these products commercially viable. If we are unable to develop or contract for manufacturing capabilities on acceptable terms for our products under development, we will not be able to conduct pre-clinical and clinical testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates and the initiation of new development programs.

Our blood screening products must be manufactured in compliance with guidelines set forth by the FDA s Center for Biologics Evaluation and Research, and our clinical diagnostic products must be manufactured in compliance with the guidelines set forth by the FDA s Center for Devices and Radiological Health. Maintaining compliance with more than one division of the FDA adds complexity and cost to our overall manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies, and these facilities are subject to Quality System Regulations requirements of the FDA. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

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

The FDA and governmental bodies in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to product manufacturing, product quality labeling, advertising, or promotional activities, or if new information is obtained concerning the safety of a product. A government-mandated recall, or a voluntary recall by us, could divert managerial and financial resources and harm our reputation with customers.

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In the past, we have had four voluntary recalls. The first product recall occurred in September 1999, when we responded to customer complaints about an increase in the number of our Mycobacterium Tuberculosis Direct, or MTD, assays demonstrating lower amplification of some test specimens. The formulation problem was identified and corrected. The second recall occurred in February 2000 when we recalled our MTD product due to decreased stability of a reagent in certain kit lots. The problem was identified and rectified through a voluntary field correction. The third recall occurred in July 2002 following the discovery of an error in the Chiron Procleix System software used with the Procleix HIV-1/HCV blood screening assay and instruments. A review of prior test results determined that the defect did not cause any inaccurate results. The problem was rectified in a subsequent software update, which was submitted to and approved by the FDA. The fourth recall occurred in June 2004 as a result of a customer complaint about our MTD product suggesting reduced stability of one of our reagents. The problem was identified and corrected and customers were provided with replacement reagent. Our products may be subject to additional recalls in the future. Future recalls could be more difficult and costly to correct, may result in the suspension of sales of our products, and may harm our financial results and our reputation.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 17% of our total revenues for the three months ended March 31, 2005 and 15% of our total revenues for 2004. Sales by Chiron of our blood screening products outside of the United States accounted for 69% of our international revenues for the three months ended March 31, 2005 and 58% of our international revenues for 2004. Chiron has responsibility for the international distribution of our blood screening products, which includes sales in France, Australia, Singapore, New Zealand, Italy and other countries. Our sales in France and Japan that were not made through Chiron accounted for 5% and 6%, respectively, of our international sales for the three months ended March 31, 2005 and 10% and 6%, respectively, for 2004.

We expect a significant portion of our sales growth, especially with respect to our blood screening products, to come from expansion in international markets. Accordingly, we encounter risks inherent in international operations. Other than Canada, our sales are currently denominated in United States dollars, if the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. Our international sales also may be limited or disrupted by:

the imposition of government controls,

export license requirements,

economic and political instability,

price controls,

trade restrictions and tariffs,

differing local product preferences and product requirements, and

changes in foreign medical reimbursement and coverage policies and programs.

In addition, we may have difficulty introducing new products in international markets. For example, we do not believe our blood screening products will be widely adopted in Germany until we are able to offer an assay that screens for HBV, HAV, and parvo B19, as well as HIV-1 and HCV, or in Japan until we are able to offer an assay that meets particular Japanese requirements for screening for HBV, HIV-1 and HCV. Whenever we seek to enter a new international market, we will be dependent on the marketing and sales efforts of our international distributors.

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

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

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We sell our products primarily to large reference laboratories, public health laboratories and hospitals, substantially all of which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other domestic and international government programs, private insurance plans and managed care programs. Most of these third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for experimental procedures and devices.

Third-party payors reimbursement policies also may affect sales of our products that screen for more than one pathogen at the same time, such as our APTIMA Combo 2 product for screening for the causative agents of chlamydial infections and gonorrhea in the same sample. Third-party payors may choose to reimburse our customers on a per test basis, rather than on the basis of the number of results given by the test. This may result in laboratories and hospitals electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, laboratories and hospitals likely would purchase separate tests for each disease, rather than products that test for more than one microorganism.

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

Disruptions in the supply of raw materials from our single source suppliers, including the Roche Molecular Biochemicals division of Roche Diagnostics GmbH, which is an affiliate of one of our primary competitors, could result in a significant disruption in sales and profitability.

We purchase some key raw materials used in the manufacture of our products from single-source suppliers. We may not be able to obtain supplies from replacement suppliers on a timely or cost-effective basis. For example, our current supplier of key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is the Roche Molecular Biochemicals division of Roche Diagnostics GmbH, an affiliate of Roche Molecular Systems, which is one of our primary competitors and the purchaser of Boehringer-Mannheim GmbH, with whom we had originally contracted for supplies. A reduction or stoppage in supply while we seek a replacement supplier would limit our ability to manufacture our products, which could result in a significant reduction in sales and profitability. In addition, an impurity or variation in a raw material, either unknown to us or incompatible with our products, could significantly reduce our ability to manufacture products. Our inventories may not be adequate to meet our production needs during any prolonged interruption of supply. We have products under development which, if developed, may require us to enter into additional supplier arrangements. We also have single source suppliers for proposed future products. Failure to maintain existing supply relationships or obtain suppliers for our future products, if any, on commercially reasonable terms, would prevent us from manufacturing our future products and limit our growth.

We are dependent on technologies we license, and if we fail to license new technologies and rights to particular nucleic acid sequences for targeted diseases in the future, we may be limited in our ability to develop new products.

We are dependent on licenses from third parties for some of our key technologies. For example, our patented Transcription-Mediated Amplification technology is based on technology we have licensed from Stanford University and the chemiluminescence technology we use in our products is based on technology licensed by our consolidated subsidiary, Molecular Light Technology Limited, from the University of Wales College of Medicine. If our license with respect to any of these technologies is terminated for any reason, we will not be able to sell products that incorporate the technology. In addition, although our research staff seeks to discover particular nucleic acid sequences

for targeted diseases, our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Likewise, our ability to design products that target these diseases may be based on our ability to obtain the necessary rights from third parties who make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT assays may be economically viable. If we are unable to obtain access to new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

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

Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of any one of our management personnel, particularly Henry L. Nordhoff, our Chairman, President and Chief Executive Officer, or our inability to identify, attract, retain and integrate additional qualified management personnel, could make it difficult for us to manage our business successfully, attract new customers, retain existing customers and pursue our strategic objectives. Currently, our positions of Vice President, Marketing and Vice President, Sales are vacant and we are now recruiting for these functions. Although we have employment agreements with our executive officers, we may be unable to retain our existing management. We do not maintain key person life insurance for any of our executive officers.

Similarly, competition for skilled sales, marketing, research, product development, engineering, and technical personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of the services of any key sales, marketing, research, product development, engineering, and technical personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop new products or enhance existing products in a timely manner, sell products to our customers or manage our business effectively.

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

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

As part of our business strategy, we intend to pursue acquisitions of other complementary businesses and technology licensing arrangements. We also intend to pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. We have limited experience with respect to acquiring other companies and with respect to the formation of collaborations, strategic alliances and joint ventures. If we make future acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license or strategic alliance.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our equity is low or volatile, we may not be able to acquire other companies. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with these regulations and develop products compatible with these regulations.

The clinical diagnostic and blood screening products we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory approvals, particularly from the FDA and some foreign governmental authorities, to market our products can be costly and time consuming, and approvals might not be granted for future products on a timely

basis, if at all. For example, we were prohibited from commercially marketing our blood screening products in the United States until we obtained approval of our Biologics License Application from the FDA s Center for Biologic Evaluation and Research. We generally are prohibited from marketing our clinical diagnostic products in the United States unless we obtain either 510(k) clearance or premarket approval from the FDA. Delays in receipt of, or failure to obtain, clearances or approvals for future products could result in delayed, or no, realization of product revenues from new products or in substantial additional costs which could decrease our profitability.

In addition, we are required to continue to comply with applicable FDA and other material regulatory requirements once we have obtained clearance or approval for a product. These requirements include, among other things, the Quality System Regulation, labeling requirements, the FDA s general prohibition against promoting products for unapproved or off-label uses and adverse event reporting regulations. Failure to comply with applicable FDA product regulatory requirements could

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result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications and criminal prosecution. Any of these actions, in combination or alone, could prevent us from selling our products.

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

As both the FDA and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Our products and operations also are often subject to the rules of industrial standards bodies, such as the International Standards Organization. Complying with these rules and regulations could cause us to incur significant additional expenses, which would harm our operating results.

The use of our diagnostic products is also affected by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and related federal and state regulations which provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some clinical laboratories from using any or all of our diagnostic products.

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

We manufacture all of our products in our two manufacturing facilities located in San Diego, California. These facilities and the manufacturing equipment we use to produce our products would be costly to replace and could require substantial lead time to repair or replace. The facilities may be harmed by natural or man-made disasters, including, without limitation, earthquakes and fires, and in the event they were affected by a disaster, we would be forced to rely on third-party manufacturers. In the event of a disaster, we may lose customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.

Our research and development activities and our manufacturing activities involve the controlled use of infectious diseases, potentially harmful biological materials, as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury, and we could be held liable for damages that result from such contamination or injury. In addition, we are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The damages resulting from any accidental contamination and the cost of compliance with environmental laws and regulations could be significant.

The anti-takeover provisions of our certificate of incorporation and by-laws, provisions of Delaware law and our rights plan could delay or prevent a change of control that you may favor.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws also may discourage, delay or prevent a merger or other change of control that stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management. The provisions of our amended and restated certificate of incorporation and amended and restated bylaws, among other things:

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divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms,

limit the right of stockholders to remove directors,

regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders, and

authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

In addition, because we have not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that you may favor. Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15 percent of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or its affiliate crosses the 15 percent stock ownership threshold.

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

We may not successfully integrate acquired businesses or technologies.

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

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

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

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

the exposure to unknown liabilities;

higher than expected acquisition and integration costs that would cause our quarterly and annual operating results to fluctuate;

increased amortization expenses if an acquisition results in significant goodwill or other intangible assets;

combining the operations and personnel of acquired businesses with our own, which would be difficult and costly; and

integrating or completing the development and application of any acquired technologies, which would disrupt our business and divert our management s time and attention.

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

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

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Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected revenue fluctuations and affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, in December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. In April 2005, the SEC approved a vote that will effectively require us to adopt this statement on January 1, 2006. This statement eliminates the ability to account for stock-based compensation using the intrinsic value method allowed under APB 25 and requires such transactions to be recognized as compensation expense in the statement of income based on the fair values on the date of grant, with the compensation expense recognized over the period in which an employee or director is required to provide service in exchange for the stock award. This new requirement will negatively impact our earnings. For example, recording a charge for employee and director stock options under SFAS No. 123(R) would have reduced our net income by $3.6 million and $1.9 million for the three months ended March 31, 2005 and 2004, respectively.

Systems implementation issues could disrupt our internal operations and adversely affect our financial results.

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have recently implemented a new general ledger information system and data warehouse to replace our various legacy systems. As a part of this effort, we are transitioning data and changing processes that may be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the continued implementation of this new system or any future systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flow and to otherwise operate our business, which could adversely affect our financial results, stock price and reputation.

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

From time to time in press releases, conference calls and otherwise, we may publish or make forecasts or other forward looking statements regarding our future results, including estimated earnings per share and other operating and financial metrics. Our forecasts are based upon various assumptions that are subject to significant uncertainties and any number of them may prove incorrect. For example, our estimated earnings per share are based in part upon a forecast of our weighted average shares outstanding at the time of our estimate. Our achievement of any forecasts depends upon numerous factors, many of which are beyond our control. Consequently, our performance may not be consistent with management forecasts. Variations from forecasts and other forward looking statements may be material and adverse and could adversely affect our stock price and reputation.

Compliance with changing corporate governance and public disclosure regulations may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq Stock Market rules, are creating uncertainty for companies such as ours. To maintain high standards of corporate governance and public disclosure, we intend to invest all reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from

revenue-generating activities.

Available Information

Copies of our public filings are available on our Internet website at http://www.gen-probe.com as soon as reasonably practicable after we electronically file such material with, or furnish them to, the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

We are exposed to foreign exchange risk for expenditures in certain foreign countries, but the total receivables and payables denominated in foreign currencies at March 31, 2005 were not material. We believe that our business operations are not exposed to market risk relating to commodity price risk.

Item 4. Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, 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 quarter ended March 31, 2005.

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 has included certain internal control areas in which we have made and are continuing to make changes to improve and enhance controls. During the first quarter of 2005, we implemented an Enterprise Resource Planning (ERP) system which is expected to improve and enhance internal controls over financial reporting. This ongoing implementation has materially changed how transactions are being processed and has also changed the structure and operation of some internal controls. While the ERP changes materially affected our internal control over financial reporting during the current quarter, the implementation has proceeded to date without material adverse effects on our internal control over financial reporting.

Except for the ERP implementation described above, there have been no other changes in our internal control over financial reporting during the quarter ended March 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We maintain disclosure controls and procedures and internal controls that are designed to ensure that information required to be disclosed in our current and periodic 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 and internal controls, 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.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 11 Litigation of the Notes to Condensed Consolidated Financial Statements included in Item 1 of Part I of this report and is incorporated by reference herein. See Notes to Condensed Consolidated Financial Statement Note 11 Litigation. We are also engaged in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material

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adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. If any of these matters were resolved in a manner unfavorable to us, our business, financial condition and results of operations would be harmed.

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Item 6. Exhibits

Exhibit Number	Description
2.1(1)	Separation and Distribution Agreement, dated and effective as of May 24, 2002, and amended and restated as of August 6, 2002, by and between Chugai Pharmaceutical Co., Ltd. and Gen-Probe Incorporated.
3.1(1)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(5)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(1)	Form of Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(5)	Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)	Specimen common stock certificate.
4.2(2)	Rights Agreement, dated as of September 16, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C.
4.3(3)	First Amendment to Rights Agreement, dated October 9, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC.
4.4(4)	Second Amendment to Rights Agreement, dated November 20, 2003.
10.79	Modified Blood Screening Instrument eSAS 2 Addendum effective January 1, 2002 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.*
10.80	Amendment No. 6 effective January 1, 2004 to Agreement dated as of June 11, 1998 between Gen-Probe Incorporation and Chiron Corporation.*
10.81	Supply and Purchase Agreement between Gen-Probe Incorporated, F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc. effective February 15, 2005.*
10.82	Amendment dated February 1, 2005 to Deferred Issuance Restricted Stock Conversion Agreement, Deferred Issuance Award Agreement and Election Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated October 8, 2004.
31.1	Certification dated May 6, 2005, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification dated May 6, 2005, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1	Certification dated May 6, 2005, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification dated May 6, 2005, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

Filed herewith.

Indicates management contract or compensatory plan, contract or arrangement.

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

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

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

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

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

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* Gen-Probe has requested confidential treatment with respect to certain portions of this exhibit. The confidential portions of this exhibit are marked by an asterisk and have been omitted and filed separately with the SEC pursuant to Gen-Probe s request for confidential treatment.

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SIGNATURES

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

DATE: May 10, 2005

By: /s/ Henry L. Nordhoff

Henry L. Nordhoff
Chairman, President and Chief Executive Officer (Principal Executive Officer)

DATE: May 10, 2005

By: /s/ Herm Rosenman

Herm Rosenman
Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)