GEN PROBE INC
Form 10-Q
August 09, 2004

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

FORM 10-Q

(Mark One)

[ü] Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended June 30, 2004

OR

[ ] 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)

(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 July 30, 2004, there were 49,604,009 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

GEN-PROBE INCORPORATED

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Item 1. Financial Statements

GEN-PROBE INCORPORATED

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	June 30, 2004	December 31, 2003
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 27,952	$ 35,973
Short-term investments	164,841	120,333
Trade accounts receivable, net of allowance for doubtful accounts of $714 and $717 at June 30, 2004 and December 31, 2003, respectively	17,827	15,158
Accounts receivable other	6,939	2,555
Inventories	27,649	15,096
Deferred income taxes	9,490	10,979
Prepaid expenses and other current assets	11,480	8,783
Total current assets	266,178	208,877
Property, plant and equipment, net	67,063	65,478
Capitalized software, net	24,723	24,872
Goodwill	18,621	18,621
Other assets	6,397	6,893
Total assets	$ 382,982	$ 324,741
Current liabilities:		
Accounts payable	10,825	9,250
Accrued salaries and employee benefits	10,579	11,670
Other accrued expenses	5,317	6,085
Income taxes payable	14,218	6,191
Deferred revenue	10,775	6,681
Total current liabilities	51,714	39,877
Deferred income taxes	6,926	6,850
Deferred revenue	5,333	5,667
Deferred rent	313	323
Minority interest	2,013	1,649

Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, $.0001 par value per share; 200,000,000 shares authorized, 49,590,728 and 48,721,560 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	5	5
Additional paid-in capital	228,019	212,586
Deferred compensation	(1,283)	(538)
Accumulated other comprehensive income	474	343
Retained earnings	89,468	57,979
Total stockholders equity	316,683	270,375
Total liabilities and stockholders equity	$ 382,982	$ 324,741

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Revenues:				
Product sales	$ 52,600	$ 46,299	$ 107,630	$ 89,919
Collaborative research revenue	7,007	3,840	13,738	5,737
Royalty and license revenue	1,618	543	16,343	1,194
Total revenues	61,225	50,682	137,711	96,850
Operating expenses:				
Cost of product sales	13,164	11,055	27,028	23,974
Research and development	15,896	16,422	34,315	27,655
Marketing and sales	6,578	5,892	13,390	10,547
General and administrative	7,476	5,391	14,759	10,017
Total operating expenses	43,114	38,760	89,492	72,193
Income from operations	18,111	11,922	48,219	24,657
Other income (expense):				
Minority interest	(83)		(179)	
Interest income	186	426	1,026	883
Interest expense	(4)	(29)	(13)	(43)
Other income (expense), net	(78)	59	(136)	66
Total other income (expense)	21	456	698	906
Income before income taxes	18,132	12,378	48,917	25,563
Income tax expense	6,371	4,229	17,428	8,760
Net income	$ 11,761	$ 8,149	$ 31,489	$ 16,803

Net income per share[1]:				
Basic	$ 0.24	$ 0.17	$ 0.64	$ 0.35
Diluted	$ 0.23	$ 0.17	$ 0.62	$ 0.35
Weighted average shares outstanding[1]:				
Basic	49,302	47,650	49,103	47,624
Diluted	51,402	48,466	51,200	48,059

(1) All share and per share amounts reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003.

See accompanying notes to consolidated financial statements.

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GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Six Months Ended June 30,	
	2004	**2003**
Operating activities		
Net income	$ 31,489	$ 16,803
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,361	7,922
Stock compensation charges	199	
Loss on disposal of property and equipment	27	58
Deferred rent	(10)	1
Stock option income tax benefits	2,220	
Deferred revenue	3,760	1,789
Deferred income taxes	1,662	153
Minority interest	249	
Changes in assets and liabilities:		
Accounts receivable	(6,460)	(2,423)
Inventories	(12,546)	(39)
Prepaid expenses and other current assets	(2,696)	(2,244)
Accounts payable	1,565	(989)
Accrued salaries and employee benefits	(1,091)	(740)
Other accrued expenses	(1,412)	(71)
Income taxes payable	8,066	(1,597)
Net cash provided by operating activities	33,383	18,623
Investing activities		
Proceeds from sales and maturities of short-term investments	108,958	22,729
Purchases of short-term investments	(153,173)	(40,663)
Purchases of property, plant and equipment	(8,824)	(6,143)
Capitalization of software development costs	(270)	(983)
Capitalization of patent costs	(284)	(298)
Other assets	(394)	(90)
Net cash used in investing activities	(53,987)	(25,448)

Financing activities		
Proceeds from issuance of common stock	12,269	1,964
Net cash provided by financing activities	12,269	1,964
Effect of exchange rate changes on cash	314	
Net increase (decrease) in cash and cash equivalents	(8,021)	(4,861)
Cash and cash equivalents at the beginning of the period	35,973	43,118
Cash and cash equivalents at the end of the period	27,952	38,257
Supplemental disclosure of cash flow information:		
Cash paid (received) for:		
Interest	$ 9	$ 37
Income taxes	$ 6,587	$ 10,241

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 June 30, 2004, and for the three and six month periods ended June 30, 2004 and 2003, 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, 2004.

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, 2003.

Note 2 Reporting periods

The Company operates and reports on fiscal periods ending on the Friday closest to the end of the month except for year-end, which closes December 31. For ease of presentation, the quarterly reporting periods are deemed to end on March 31, June 30 and September 30. The three months ended March 31, 2004 and six months ended June 30, 2004 included three more business days compared to the same periods in the prior year.

Note 3 Summary of significant accounting policies

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales and Services, Inc., Gen-Probe Canada, Inc., Gen-Probe UK Limited and Molecular Light Technology Limited and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

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

Foreign currency translation

The functional currency of the Company s majority owned subsidiary, Molecular Light Technology Limited and its subsidiaries, is the British pound. Accordingly, all balance sheet accounts of this subsidiary 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 this subsidiary s 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

In June 2004, the Company granted 20,000 shares of restricted common stock to its chief executive officer under the 2003 Incentive Award Plan of Gen-Probe Incorporated (the 2003 Plan), resulting in deferred compensation of $839,000 associated with this grant. The deferred compensation is being amortized to expense over the vesting period of the restricted stock.

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The Company measures compensation expense for its employee stock-based compensation using the intrinsic value method and provides pro forma disclosures of net income and earnings per common share as if the fair value methods had been applied in measuring compensation expense. Under the intrinsic value method, compensation cost for employee stock awards is recognized as the excess, if any, of the deemed fair value for financial reporting purposes of the Company s common stock on the date of grant over the amount an employee must pay to acquire the stock.

Pro forma information regarding net income is required to be disclosed in interim financial statements by Statement of Accounting Standards (SFAS) No. 148, and has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method of SFAS No. 123. The fair value for employee stock options was estimated at the dates of grant using the minimum value option pricing model from the stock option plan inception date in 2000 through September 15, 2002 and the Black-Scholes pricing model for all option grants made subsequent to that date. The following weighted average assumptions were used:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Risk free interest rate	3.60%	2.27%	3.19%	2.38%
Dividend yield	0%	0%	0%	0%
Volatility factor	64%	50%	66%	50%
Expected life (in years)	4	4	4	4
Resulting average fair value	$ 20.68	$ 6.70	$ 18.64	$ 6.24

The fair value of each purchase right issued under the Company s Employee Stock Purchase Plan (ESPP) for the three and six month periods ended June 30, 2004 and 2003 was estimated on the date of grant using the Black-Scholes pricing model. The following weighted average assumptions were used:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Risk free interest rate	1.0%	1.0%	1.0%	1.0%
Dividend yield	0%	0%	0%	0%
Volatility factor	66%	54%	59%	54%
Expected life (in years)	.50	.20	.50	.20
Resulting average fair value	$ 6.33	$ 1.80	$ 5.46	$ 1.80

Had compensation expense for stock-based compensation plans been determined based on the fair value method prescribed under SFAS No. 123, the Company s net income and net income per share would have been as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Net income:				
As reported	$ 11,761	$ 8,149	$ 31,489	$ 16,803
Stock-based employee compensation expense included in reported net income, net of related tax effects	33		55	
Total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(2,397)	(234)	(4,289)	(418)
Pro forma net income	$ 9,397	$ 7,915	$ 27,255	$ 16,385
Net income per share:				
As reported				
Basic	$ 0.24	$ 0.17	$ 0.64	$ 0.35
Diluted	$ 0.23	$ 0.17	$ 0.62	$ 0.35
Pro forma				
Basic	$ 0.19	$ 0.17	$ 0.56	$ 0.34
Diluted	$ 0.18	$ 0.16	$ 0.53	$ 0.34

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The pro forma effects on net income for the three and six month periods ended June 30, 2004 and 2003 are not likely to be representative of the effects on reported net income in future years. In management s opinion, existing stock option valuation models do not provide a reliable single measure of the fair value of employee stock options that have vesting provisions and are not transferable. In addition, option valuation models require the input of highly subjective assumptions, and changes in such subjective assumptions can materially affect the fair value estimate of employee stock options.

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. Basic net income per share is computed based on the weighted average number of common shares outstanding during the period. Diluted net income per share is computed based on the weighted average number of shares of common stock and other dilutive securities 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 following table sets forth the computation of net income per share (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Net income	$ 11,761	$ 8,149	$31,489	$16,803
Weighted average shares outstanding Basic	49,302	47,650	49,103	47,624
Effect of dilutive common stock options outstanding	2,100	816	2,097	435
Weighted average shares outstanding Diluted	51,402	48,466	51,200	48,059
Net income per share:				
Basic	$ 0.24	$ 0.17	$ 0.64	$ 0.35
Diluted	$ 0.23	$ 0.17	$ 0.62	$ 0.35

Dilutive securities include common stock options subject to vesting and unvested restricted stock. Potentially dilutive securities totaling 225,636 and 135,564 for the three months ended June 30, 2004 and 2003, and 307,086 and 179,200 shares for the six months ended June 30, 2004 and 2003, 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 June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Net income	$ 11,761	$ 8,149	$31,489	$16,803
Foreign currency translation adjustment	(412)		504	
Change in unrealized gain (loss) on investments	(196)	150	(373)	206
Comprehensive income	$ 11,153	$ 8,299	$31,620	$17,009

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Note 7 Inventories

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

	June 30, 2004	December 31, 2003
Raw materials	$ 7,540	$ 5,874
Work in progress	6,569	3,118
Finished goods	13,540	6,104
	$ 27,649	$ 15,096

Note 8 Stockholders equity

Number of authorized shares of common stock

On September 5, 2003, the Company s Board of Directors authorized a two-for-one stock split implemented as a 100% stock dividend, effective September 30, 2003 for holders of record as of September 16, 2003 (the Stock Split). As a result of the Stock Split by stock dividend, the number of outstanding shares of the Company s common stock and the number of shares of the Company s common stock reserved under its equity compensation plans was doubled. On May 28, 2004, the Company s stockholders approved an increase in the authorized number of shares of common stock under the Company s Certificate of Incorporation from 100,000,000 to 200,000,000 shares.

Common stock

During the three and six months ended June 30, 2004, 514,118 and 809,647 options, respectively to purchase shares of the Company s common stock were exercised by Gen-Probe employees at a weighted average exercise price of $13.42 and $13.22, respectively. The Company also issued 719 and 2,804 shares of restricted common stock at fair market value during the three and six months ended June 30, 2004, respectively to members of the Board of Directors as partial consideration for services rendered, resulting in an expense totaling $34,023 and $106,535, respectively, which was equal to the fair market value on the date of grants. Further, employees purchased 56,717 shares of the Company s common stock at an average purchase price of $26.92 per share during the six months ended June 30, 2004, pursuant to the Company s ESPP.

Note 9 Litigation

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

Enzo Biochem, Inc.

In June 1999, the Company was sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that the Company and its former affiliates, as well as Becton Dickinson and bioMérieux, have willfully infringed United States patent no. 4,900,659, or the 659 patent, through the manufacture and sale of products for the diagnosis of gonorrhea. The Company s former affiliates and bioMérieux have been dismissed from the case by Enzo. The Company and Becton Dickinson remain as defendants. Enzo asserted a damage claim based on a contention that Enzo was entitled to a reasonable royalty on all sales of Gen-Probe products for the detection of *Neisseria gonorrhoeae* bacteria from June 1993 through trial. Revenues from tests for the detection of *Neisseria gonorrhoeae* have constituted a significant portion of Gen-Probe s revenues during the relevant period. The Company believes that the claims of the 659 patent are invalid, unenforceable and may not be properly interpreted to cover its products. On July 27, 2004, the Court granted summary judgment in favor of the defendants and against Enzo, holding that the 659 patent is invalid based on an on-sale doctrine. Enzo has indicated that it plans to appeal the summary judgment to the United States Court of

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Appeals for the Federal Circuit. The Company intends to vigorously defend the lawsuit. However, there can be no assurance that the case will be resolved in the Company s favor.

Vysis, Inc.

In December 1999, the Company initiated litigation in the United States District Court for the Southern District of California against Vysis, now a subsidiary of Abbott Laboratories, seeking a declaratory judgment that the Company s products were not covered by a Vysis patent that is the subject of a license granted by Vysis in favor of the Company and that the patent is invalid and unenforceable. In August 2002, following a jury trial, the District Court entered judgment in the Company s favor, finding the Vysis patent invalid and finding that the patent does not cover Gen-Probe s products. On September 3, 2002, Vysis filed a notice of appeal with the District Court. Further, on October 22, 2002 while Vysis appeal was pending, the United States Patent & Trademark Office reissued the Vysis patent with amended claims. On October 22, 2002, the Company filed a second lawsuit in District Court to challenge the validity and scope of the reissued patent. On March 5, 2004, the Court of Appeals vacated the District Court s August 2002 judgement in favor of the Company and directed the District Court to dismiss the case on the ground of lack of subject matter jurisdiction. The Company s petition for rehearing and rehearing en banc (with the participation of all the judges) was denied by the Federal Circuit. In accordance with the denial, on July 14, 2004, the District Court dismissed the action with prejudice. The Company intends to file a petition for review by the United States Supreme Court of the lower court s decision. There can be no assurances as to the final outcome of this litigation. The Company has at all times maintained the license with Vysis in full force and continued to make royalty payments under the license, pending final resolution of the litigation.

Bayer Corporation

In November 2002, the Company filed a demand for arbitration against Bayer Corporation, or Bayer, in the Judicial Arbitration & Mediation Services, Inc., or JAMS, office in San Diego, California related to the Company s collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of HIV, hepatitis viruses and other specified viruses, subject to certain conditions. Gen-Probe s demand for arbitration states that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. The arbitration demand seeks confirmation that the agreement grants Gen-Probe, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. Gen-Probe s arbitration demand also seeks money damages due to Bayer s failure to use commercially reasonable efforts to promote, market and sell viral diagnostic assays developed by Gen-Probe. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS system, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC has also been added as a respondent and counterclaimant. The matter has been set for hearing beginning September 13, 2004. There can be no assurances as to the final outcome of the arbitration.

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

Item 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 June 30, 2004 consolidated financial statements and related notes thereto and with our consolidated financial statements and notes thereto for the year ended December 31, 2003 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, 2003. 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

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year ended December 31, 2003.

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for the screening of donated human blood. We have over 21 years of nucleic acid detection research and product development experience, and our products, which are based on our patented nucleic acid testing, or NAT, technology, are used daily in clinical laboratories and blood collection centers in major countries throughout the world.

In September 2002, our common stock began trading on the Nasdaq National Market immediately after our former parent company, Chugai Pharmaceutical Co., Ltd. distributed all of its shares of our common stock to its shareholders. Since our spin-off into an independent, publicly traded company, we have achieved strong growth in both revenues and earnings due principally to the success of our blood screening products which are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, and hepatitis C virus, or HCV. Under our collaboration agreement with Chiron Corporation, or Chiron, we are responsible for the research, development, regulatory process and manufacturing of our blood screening products, while Chiron is responsible for marketing, sales, distribution and service.

During the three and six months ended June 30, 2004, we achieved strong financial results. Net income for the six month period ended June 30, 2004 was $31.5 million ($0.62 per diluted share), compared to $16.8 million ($0.35 per diluted share) in the same period of the prior year, an increase of 77% per diluted share. Total revenues for the six month period ended June 30, 2004 were $137.7 million, compared to $96.9 million in the same period of the prior year, an increase of 42%. Product sales for the period ended June 30, 2004 were $107.6 million, compared to $89.9 million in the same period of the prior year, an increase of 20%. During the six month period ended June 30, 2004, net income and total revenues included a contract milestone with Chiron and a license fee 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.

Recent Events

The launch of the Tigris system was slower than expected early in the year, but picked up speed in the second quarter. Between assay revenues and instrument sales, we remain on track to achieve $5 million or more in TIGRIS-related revenue this year.

Clinical trials of the Procleix Ultrio blood screening assay on both the semi-automated and TIGRIS systems have been completed on schedule. Gen-Probe remains on track to file a Biologics License Application (BLA) for the assay in the third quarter of 2004.

The pivotal clinical trial of the Procleix WNV assay began on schedule in July 2004, and we remain on track to file a BLA for the assay in the first quarter of 2005. So far this mosquito season, the assay has intercepted 42 confirmed West Nile virus, or WNV, infected blood donations in nine states through ongoing screening under an Investigational New Drug, or IND. In addition, Gen-Probe expects to begin IND testing of the Procleix WNV assay on the fully automated TIGRIS system in August.

We successfully completed the process of transferring DiagnoCure s first-generation assay for prostate cancer detection onto our APTIMA technology platform, and development work is proceeding well.

We have completed clinical trials to evaluate APTIMA Combo 2 to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from both Cytyc Corporation s and TriPath Imaging Inc. s liquid Pap transport media. The Pap test remains the most widely used screening test in the United States for the early detection of cervical cancer. Approximately 50 million Pap tests are performed annually in the United States, 80% of which are liquid-based. Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from the liquid Pap medium would offer patients, physicians and laboratories convenient testing for several diseases from one sample, and further differentiate the superior performance of APTIMA Combo 2 in the widest range of specimen types. We intend to file for United States regulatory clearance later this year.

In December 2003, we signed a cross-licensing agreement with Tosoh, effective January 1, 2004, for certain NAT technologies in clinical diagnostics and other related fields. Under the agreement, we earned a $7.0 million license fee during the three months ended March 31, 2004.

In January 2004, we began United States clinical trials of the Procleix Ultrio assay on the fully automated, high-throughput TIGRIS instrument system, triggering a $6.5 million contract milestone payment from Chiron that we recognized during the three months ended March 31, 2004. During January 2004, the Procleix Ultrio assay, running on our semi-automated instrument system, received its

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Community European, or CE, mark, which permitted Chiron to launch the product in the European Economic Area.

Revenues

We derive revenues from three primary sources: product sales, collaborative research revenue and royalty and license revenue. The majority of our revenues come from product sales, which consist primarily of sales of our NAT assays tested on the proprietary instruments that serve as the analytical platform for our assays. We recognize as collaborative research revenue payments we receive from Chiron for the products we provided under our collaboration agreements with Chiron prior to their regulatory approval and the payments we receive from Chiron, Bayer Corporation, or Bayer, and other collaboration partners, including the National Institutes of Health, or NIH, for research and development activities. Our royalty and license revenues reflect fees paid to us by third parties for the use of our proprietary technology. For the six months ended June 30, 2004, product sales, collaborative research revenues, and royalty and license revenues equaled 78%, 10% and 12%, respectively, of our total revenues of $137.7 million. For the same period in the prior year, product sales, collaborative research revenues, and royalty and license revenues, equaled 93%, 6% and 1%, respectively, of our total revenues of $96.9 million.

Product sales

Our primary source of revenue is the sale of clinical diagnostic products in the United States, which include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During the six months ended June 30, 2004, we shipped approximately 10.8 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 first blood screening assay detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments are marketed through our collaboration with Chiron under the Procleix and Ultrio trademarks. We recognize product sales from the manufacture and shipment of tests for screening donated blood, through our collaboration with Chiron, to blood bank facilities located in the countries where our products have obtained governmental approvals at a contractual transfer price. 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, which was 43.0% with respect to sales of assays that include a test for HCV beginning the second quarter of 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 developed a NAT assay to detect HIV-1 and HCV in donated human blood and have also developed a semi-automated instrument system to conduct the test. These assays and instruments are marketed through our collaboration with Chiron under the Procleix name. In February 2002, the Food and Drug Administration, or FDA, approved the Procleix HIV-1/HCV assays.

In March 2003, we signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. For the six month periods ended June 30, 2004 and 2003, we recognized $1.3 million and $2.8 million, respectively in reimbursements for expenses incurred related to the development of this assay. In January 2004, we commenced clinical trials of the Procleix Ultrio assay in the United States on our TIGRIS instrument. We have also developed a NAT assay to detect WNV, which is currently being used in clinical trials under an IND application. We expect to receive further reimbursement for certain costs incurred during the development of the Procleix Ultrio and WNV assays from Chiron and separately from the National Heart, Lung, and Blood Institute, a part of the NIH.

We have recorded revenues related to use of our blood screening products in the United States and other countries in which the

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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 the six months ended June 30, 2004, we recognized $9.2 million in collaborative research revenue through our collaboration with Chiron from deliveries of WNV tests on a cost recovery basis. We expect to continue recognizing these sales as collaborative research revenue until FDA approval has been received, although there is no guarantee we ultimately will receive FDA approval.

Since 1996, we have been awarded contracts aggregating approximately $28.2 million by the NIH to develop NAT assays for screening donated blood for HIV-1, HCV, hepatitis B virus, or HBV, and WNV. To date, all payments due to us under these reimbursement contracts have been received and have been recorded as collaborative research revenues as reimbursable costs were incurred. As of June 30, 2004, the Company had approximately $0.2 million in reimbursements remaining under this contract, which will be recognized during the third quarter of 2004 as expenses are incurred.

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

Collaborative research revenue tends to fluctuate based on the amount of research services performed, delivery of assays on a cost recovery basis and the status of projects under collaboration. 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, maintain and perform under relationships with potential and current collaborative partners. These relationships may not be established or maintained and current collaborative research revenue may decline.

Royalty and license revenue

We recognize non-refundable up-front license fees over the performance period of the applicable agreement or at the time that we have satisfied all substantive performance obligations under such agreement. We also receive milestone payments for successful achievement of contractual development activities. Milestone payments are recognized as revenue upon achievement of the milestone only if there are no remaining substantive performance obligations under such agreement and the amounts are non-refundable.

In December 2003, we entered into an agreement with Tosoh to cross-license intellectual property covering certain NAT technologies. The licenses, which were effective January 1, 2004, cover products in clinical diagnostics and other related fields. Under the agreement, Tosoh received non-exclusive rights to our proprietary Transcription-Mediated Amplification, or TMA, and rRNA technologies in exchange for two payments totaling $7.0 million, which was recognized as revenue in the first quarter of 2004. Additionally, Tosoh will pay us royalties on worldwide sales of any future products that employ our technologies licensed by Tosoh. We will gain access, in exchange for the payment of royalties, to Tosoh s patented Transcription Reverse-Transcription Concerted, or TRC, amplification and Intercalation Activating Fluorescence, or INAF, detection technologies for use with our real time TMA technology.

Under the strategic alliance agreement we entered into with Chiron in June 1998, we have responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Chiron has responsibility for marketing, distribution and service of the blood screening products worldwide. During the first

quarter of 2004, the Company recognized as royalty and license revenue, a $6.5 million milestone payment, as the Company began clinical trial tests of the Procleix Ultrio assay on the TIGRIS instrument in the United States. Additional payments of up to $10.0 million are due to us in the future under the agreement if we achieve certain other specified milestones relating to the development of the TIGRIS instrument. There is no guarantee we will receive any additional milestone payments under this agreement.

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

Cost of product sales

Cost of product sales includes direct material, direct labor, and manufacturing overhead associated with the production of inventory

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

In addition, we manufacture significant quantities of raw materials, development lots, and clinical trial lots of product prior to receiving FDA approval for commercial sale. During the six month periods ended June 30, 2004 and 2003, our manufacturing facilities produced development lots for WNV and Procleix Ultrio assays. The majority of the costs associated with these development lots are classified as research and development expense. The portion of a development lot that is manufactured to support In-Vitro Diagnostic, or IVD, sales abroad is capitalized and classified as cost of sales upon shipment.

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

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

Research and development

We invest significantly in research and development as part of our ongoing efforts to accelerate the development of new products and technologies, particularly our TIGRIS instrument and our Procleix Ultrio and WNV assays for screening donated blood. Our research and development expenses consist of expenses associated with the development of proprietary products and instrument platforms, as well as expenses related to the co-development of new products and technologies in collaboration with our strategic partners. Research and development costs in total are expected to increase in the future due to new product development, clinical trial costs and clinical manufacturing costs; however, we expect our research and development expenses as a percentage of total revenues to decline in future 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 research and development efforts, we have various license agreements, which provide us with rights to develop and market products using certain technologies and patent rights maintained by third parties. These agreements generally provide for a term that commences upon execution of the agreement and continues until expiration of the last patent related to the technologies covered by the license.

Research and development costs 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 the remainder of 2004, we expect to incur additional incremental costs associated with the manufacture of developmental lots and clinical trial lots for our blood screening products and with the TIGRIS instrument. Collaborative research revenues, if any, associated with these types of incurred costs have typically been realized in a period later than when incurred.

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

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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 under different assumptions or conditions.

We believe there have been no significant changes to our critical accounting policies and estimates as disclosed 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, 2003, except for the item(s) discussed below.

Capitalized software costs

We capitalize costs incurred in the development of computer software related to products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product.. At June 30, 2004, capitalized software development costs related to our TIGRIS instrument totaled $24.7 million, net. We completed beta evaluations of this instrument for clinical diagnostic applications and undertook initial beta trials for blood screening applications in the third quarter of 2002 and we completed a clinical trial for a diagnostic application in June 2003. In December 2003, we received approval from the FDA for testing certain STDs on the TIGRIS instrument. We initiated clinical trials of our Procleix Ultrio assay on the TIGRIS instrument for a blood screening application in January 2004. If we are not able to successfully deliver this instrument to the marketplace and attain customer acceptance, the asset could be impaired and an adjustment to the carrying value of this asset would be considered by management at that time.

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

Results of Operations

The following table sets forth operating data as a percentage of total revenues on a comparable basis for the three and six month periods ended June 30, 2004 and 2003. The information for each of these periods is unaudited and has been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited quarterly results when read in conjunction with our audited financial statements and related notes. Past operating results are not necessarily indicative of future results.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Total revenues	100 %	100 %	100 %	100 %
Product sales	86 %	91 %	78 %	93 %
Collaborative research revenue	11 %	8 %	10 %	6 %

Royalty and license revenue	3 %	1 %	12 %	1 %
Operating expenses:				
Cost of product sales	22 %	22 %	19 %	25 %
Research and development	26 %	32 %	25 %	29 %
Marketing and sales	11 %	12 %	10 %	11 %
General and administrative	12 %	11 %	11 %	10 %
Total operating expenses	71 %	77 %	65 %	75 %
Income from operations	29 %	23 %	35 %	25 %
Total other income (expense)	0 %	1 %	1 %	1 %
Income before income taxes	29 %	24 %	36 %	26 %
Income tax expense	10 %	8 %	13 %	9 %
Net income	19 %	16 %	23 %	17 %

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Three Months Ended June 30, 2004 Compared to Three Months Ended June 30, 2003
(Percentages have been rounded to the nearest whole percentage)

Product sales

Product sales increased $6.3 million, or 14%, to $52.6 million during the three months ended June 30, 2004, from $46.3 million in the same period of the prior year. The increase was primarily the result of a $3.6 million increase in worldwide commercial sales of our Procleix blood screening products, a $1.1 million increase in STD product sales, primarily APTIMA, and a $1.6 million increase in sales of other diagnostic products. Procleix blood screening product sales represented $22.1 million, or 42% of product sales, for the three months ended June 30, 2004, compared to $18.5 million, or 40% of product sales, for the three months ended June 30, 2003.

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

Collaborative research revenue

Collaborative research revenue increased $3.2 million, or 84%, to $7.0 million during the three months ended June 30, 2004, from $3.8 million in the same period of the prior year. The increase was primarily the result of a $4.7 million increase in firm support commitment payments in connection with the WNV tests provided to United States customers through our collaboration with Chiron. This increase was partially offset by a $0.6 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay and a $0.6 million decrease in revenue from the NIH to develop a NAT assay for the detection of WNV.

Royalty and license revenue

Royalty and license revenue increased $1.1 million to $1.6 million in the three months ended June 30, 2004, from $0.5 in the same period of the prior year. The increase was attributed to a $1.1 million increase in net license income from Bayer for the licensing of rights to certain patented technology.

Cost of product sales

Cost of product sales increased $2.1 million to $13.2 million, or 25% of product sales in the three months ended June 30, 2004, from $11.1 million, or 24% of product sales, in the same period of the prior year. The $2.1 million 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 during the period. Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales are also affected by manufacturing efficiencies, allowances for scrap or obsolete materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

Our gross profit margin on product sales decreased to 75% in the three months ended June 30, 2004, from 76% in the same period of the prior year due, in part, to the amortization of capitalized software development costs of $0.4 million, which began in the second quarter of 2004.

Research and development

Our research and development expenses include salaries and other personnel-related expenses, temporary personnel expenses, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. Research and development expenses decreased $0.5 million to $15.9 million, or 26% of total revenues, in the three months ended June 30, 2004, from $16.4 million, or 32% of total revenues, in the same period of the prior year. The decrease was primarily the result of a $4.5 million decrease in inventory used due to lower development lot production, which was partially offset by a $2.5 million increase in expenses resulting from higher staffing levels to support product development projects and a $1.1 million increase in expenses related to clinical trials for blood bank.

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Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $0.7 million to $6.6 million, or 11% of total revenues, in the three months ended June 30, 2004, from $5.9 million, or 12% of total revenues, in the same period of the prior year. The increased spending principally included expenses to support increases in sales of our clinical diagnostic products, including a $0.2 million increase for printing and promotional costs related to the marketing of TIGRIS.

General and administrative

Our general and administrative expenses include personnel costs for finance, legal, public relations, human resources and business development, as well as professional fees, such as expenses for legal, patents and auditing services. General and administrative expenses increased $2.1 million to $7.5 million, or 12% of total revenues, in the three months ended June 30, 2004, from $5.4 million, or 11% of total revenues, in the same period of the prior year. The increased spending included a $1.1 million increase in expenses resulting from higher staffing levels, including expenses from our majority owned subsidiary, Molecular Light Technology Limited (acquired in August 2003), and a $0.6 million increase in patent and legal related expenses, primarily related to the ongoing Bayer arbitration.

Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $21,000 in the three months ended June 30, 2004 represented a $435,000 decrease from the net other income of $456,000 in the same period of the prior year. The decrease was primarily due to realized market losses in our investment portfolio of government bonds, coinciding with our recent shift in investment emphasis from U.S. Treasury bonds to tax free municipal bonds, bond interest rates increased approximately 100 basis points during the second quarter of 2004, resulting in market losses for lower yield bonds as they were sold. If these available for sale securities had been held to maturity, most of these realized market losses would have been recorded through stockholders equity as other comprehensive income or loss. The Company expects to achieve a long term benefit with the tax free securities.

Income tax expense

Income tax expense increased to $6.4 million, or 35% of pretax income, in the three months ended June 30, 2004, from $4.2 million, or 34% of pretax income, in the same period of the prior year. The increased effective tax rate in 2004 is attributed to higher profits taxed at the combined Federal and state statutory tax rate of approximately 41%, partially offset by the benefit of Federal and state research and investment credits.

Six Months Ended June 30, 2004 Compared to Six Months Ended June 30, 2003
(Percentages have been rounded to the nearest whole percentage)

Product sales

Product sales increased $17.7 million, or 20%, to $107.6 million during the six months ended June 30, 2004, from $89.9 million in the same period of the prior year. The increase was primarily the result of a $10.1 million increase in worldwide commercial sales of our Procleix blood screening products, a $5.5 million increase in STD product sales, primarily APTIMA, and a $2.1 million increase in sales of our other diagnostic products. Procleix blood screening product sales represented $45.1 million, or 42% of product sales, for the six months ended June 30, 2004, compared to $35.0 million, or 39% of product sales, for the six months ended June 30, 2003.

Collaborative research revenue

Collaborative research revenue increased $8.0 million, or 140%, to $13.7 million during the six months ended June 30, 2004, from $5.7 million in the same period of the prior year. The increase was primarily the result of a $9.2 million increase in firm support commitment payments in connection with the WNV tests provided to United States customers through our collaboration with Chiron. Further, we recognized $0.5 million additional revenues from the NIH to develop a NAT assay for the detection of WNV. These increases were partially offset by a $1.5 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay. We recognized $1.3 million in revenue during the first quarter of 2003 for work performed during 2002 and 2001 in connection our collaboration with Chiron.

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Royalty and license revenue

Royalty and license revenue increased $15.1 million to $16.3 million in the six months ended June 30, 2004, from $1.2 million in the same period of the prior year. The increase was attributed to $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 $6.5 million in milestone revenue from Chiron as the Company began clinical trial testing in the United States of the Procleix Ultrio assay on the fully automated TIGRIS instrument. Additionally, we recognized $1.5 million in net license income from Bayer during the six months ended June 30, 2004 for the licensing of rights to certain patented technology.

Cost of product sales

Cost of product sales increased $3.0 million to $27.0 million, or 25% of product sales, in the six months ended June 30, 2004, from $24.0 million, or 27% of product sales, in the same period of the prior year. The $3.0 million increase in cost of sales was principally attributed to the volume increase in product sales and the amortization of capitalized software development costs.

Our gross profit margin on product sales increased to 75% in the six months ended June 30, 2004, from 73% in the same period of the prior year. The gross profit margin benefited from certain manufacturing costs absorbed by research and development for the production of pre-commercial development lots, partially offset by amortization of the TIGRIS instrument capitalized software which began in the second quarter of 2004.

Research and development

Our research and development expenses include salaries and other personnel-related expenses, temporary personnel expenses, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. Research and development expenses increased $6.6 million to $34.3 million, or 25% of total revenues, in the six months ended June 30, 2004, from $27.7 million, or 29% of total revenues, in the same period of the prior year. The increased spending was primarily the result of a $5.1 million increase in expenses resulting from higher staffing levels to support product development projects, a $2.0 million increase in expenses related to clinical trials for blood screening products and a $0.8 million increase in research and development expenses from our subsidiary, Molecular Light Technology Limited (acquired in August 2003), partially offset by a $1.6 million decrease in the unit costs of clinical lots produced for our WNV project.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $2.8 million to $13.4 million, or 10% of total revenues, in the six months ended June 30, 2004, from $10.5 million, or 11% of total revenues, in the same period of the prior year. The increased spending principally included a $2.1 million increase in salaries, benefits, commissions and other personnel related costs in our marketing and sales force to support increases in sales for our clinical diagnostic products, together with a $0.4 million increase for advertising and promotional costs related to the marketing of our TIGRIS instrument.

General and administrative

Our general and administrative expenses include personnel costs for finance, legal, public relations, human resources and business development, as well as professional fees, such as expenses for legal, patents and auditing services. General and administrative expenses increased $4.8 million to $14.8 million, or 11% of total revenues, in the six months ended June 30, 2004, from $10.0 million, or 10% of total revenues, in the same period of the prior year.

The increased spending included a $2.3 million increase in expenses resulting from higher staffing levels, including expenses from our majority owned subsidiary, Molecular Light Technology Limited (acquired in August 2003), and a $1.7 million increase in patent and legal related expenses, primarily related to the ongoing Bayer arbitration.

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Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $698,000 in the six months ended June 30, 2004 represented a $208,000 decrease from the net other income of $906,000 in the same period of the prior year. The decrease was primarily due to a $179,000 increase in minority interest expense from our subsidiary, Molecular Light Technology Limited, and a $115,000 decrease in realized foreign exchange rate losses from our sales to Canadian customers.

Income tax expense

Income tax expense increased to $17.5 million, or 36% of pretax income, in the six months ended June 30, 2004, from $8.8 million, or 34% of pretax income, in the same period of the prior year. The increased effective tax rate in 2004 is attributed to higher profits taxed at the combined Federal and state statutory tax rate of approximately 41%, partially offset by the benefit of Federal and state research and investment credits.

Liquidity and capital resources

Historically, we have financed our operations through cash from operations, cash received from collaborative research agreements, royalty and license fees, the private placement of debt and cash from capital contributions. At June 30, 2004, we had $192.8 million of cash and cash equivalents and short-term investments.

For the six months ended June 30, 2004, net cash provided by operating activities was $33.4 million, compared to $18.6 million in the same period of the prior year. The increase in net cash during the six months ended June 30, 2004 was principally the result of net income of $31.5 million, depreciation and amortization of $8.4 million and an $8.1 million increase in income taxes payable, partially offset by a $6.5 million increase in accounts receivable and a $12.5 million increase in inventory.

Our investing activities, which used cash of $54.0 million for the six months ended June 30, 2004, consisted of purchases, net of proceeds of $44.2 million for short-term investments and $8.8 million for capital expenditures. Our expenditures for capital additions vary based on the stage of 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 gives us flexibility in planning capital expenditures.

Net cash provided by financing activities for the six months ended June 30, 2004, was the result of $12.3 million in proceeds from stock option exercises and purchases made through our Employee Stock Purchase Plan, or ESPP. Cash from financing activities will be affected by receipts from sales of stock under our ESPP and from the exercise of stock options. We expect fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock, together with other factors.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2005, under which we may borrow up to $10.0 million, subject to a borrowing base formula, at the bank s prime rate, or at LIBOR plus 1.0%. We have not taken advances against the line of credit since its inception. The line of credit agreement requires us to comply with various financial and restrictive covenants. Financial covenants include requirements as to tangible net worth, liabilities as a percentage of tangible net worth, the ratio of current assets to current liabilities, required minimum levels of earnings before interest, taxes, depreciation and amortization, the ratio of funded debt to earnings before interest, taxes, depreciation and amortization, and maximum levels of pre-tax and after tax losses. At December 31, 2003 and June 30, 2004, we were in compliance with all covenants and had no

outstanding borrowings under this line of credit.

In July 2004, we commenced the construction of an additional building at our Genetic Center Drive location. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 160,000 square feet built out with interior improvements. The additional space that will not initially be built out will allow for future expansion. The first phase of this project is estimated to take two years for completion and is currently estimated to cost approximately $45.0 million. These costs will be capitalized as incurred and depreciation will commence upon our completion and use, which is planned for early 2006.

We plan to implement a new Enterprise Resource Planning, or ERP, software system, which currently is estimated to represent an approximately $6.5 to $8.0 million expenditure. The majority of these costs will be capitalized and amortization will commence upon our placement of the new ERP system into service, which is currently planned for January 2005.

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

Contractual obligations and commercial commitments

In connection with the joint development of the Procleix HIV-1/HCV assay, and as a condition for Chiron s agreement to pay for most of the clinical trial costs related to approval of that assay, we agreed to pay the costs related to the clinical trial for the next joint development project with Chiron. Our obligation is limited to the cost incurred for the previous joint clinical trial, which was approximately $4.1 million. As of June 30, 2004, we had incurred approximately $3.7 million of clinical trial expenses as a result of this obligation to Chiron and we anticipate that our obligation to pay these costs will satisfied during the second half of 2004.

In November 2003, we entered into a license and collaboration agreement with DiagnoCure under which we agreed to develop in collaboration with DiagnoCure, and we agreed to market, a test to detect a new gene marker for prostate cancer. Under the terms of the agreement, we agreed to pay DiagnoCure an upfront fee of $3.0 million, and future fees and contract development payments of up to $7.5 million over the next three years.

Our primary short-term needs for capital, which are subject to change, are for continued research and development of new products, costs related to commercialization of blood screening products and purchases of the TIGRIS instruments for placement with our customers. Certain research and development costs are funded under collaboration agreements with partners or agencies of the United States government. We anticipate additional funds from these sources as reimbursable costs are incurred, but these funds may not materialize and these relationships may not continue.

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

We may from time to time consider the acquisition of businesses and/or technologies complementary to our business. We could require debt and/or equity 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 and/or equity securities.

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. Our product revenues, particularly in bloodscreening, may vary significantly from quarter to quarter based upon fluctuations in blood donations and

reportable bloodscreening results. 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 2003 and the first half of 2004 and will continue to incur expense through the remainder of 2004 and beyond as we seek FDA approval of our Procleix Ultrio assay and the WNV assay. 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 from commercial sales of assays that test for HCV under our blood screening collaboration with Chiron decreased to 45.75% of net revenues as of January 1, 2004, as a result of the recent 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. Because of all of these factors, our operating results in one or more future quarters may fail to meet or exceed financial guidance we may provide from time to time and the expectations of

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securities analysts or investors, which could cause our stock price to decline.

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

We rely on Chiron to distribute our blood screening products and Bayer to distribute some of our viral clinical diagnostic products. Commercial product sales by Chiron accounted for 33% of our total revenues for the six months ended June 30, 2004 and 37% of our total revenues for 2003. Our agreements with Chiron and Bayer will terminate in 2010 unless extended. Both the Chiron and Bayer agreements can be extended by the development of new products under the agreements, in which case they will expire upon the later of the end of the original term or five years after the first commercial sale of the last new product developed during the original term.

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

In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by us for the detection of HIV, hepatitis virus and other specified viruses, subject to specific conditions. Our demand for arbitration stated that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. Accordingly, we are seeking confirmation that the agreement grants us, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. Our arbitration demand also seeks money damages due to Bayer s failure to use commercially reasonable efforts to promote, market and sell viral diagnostic assays developed by us. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument and certain assays, and other claims. The matter has been set for hearing beginning on September 13, 2004. There can be no assurances as to the final outcome of the arbitration.

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

decrease.

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

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

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The continuation of any of our collaboration agreements may depend on the periodic renewal of our corporate collaborations. Our agreements with Chiron and Bayer will terminate in 2010 unless extended by the development of new products under the agreements, so that they will expire upon the later of the original term or five years after the first commercial sale of the last new product developed during the original term. Both collaboration agreements are also subject to termination prior to expiration upon a material breach by either party to the agreement.

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.

Market demand for our new TIGRIS instrument may be difficult to predict. If we are unable to deliver and support the TIGRIS instrument, we may be unable to retain our existing customers and attract new customers.

We believe the fully-automated TIGRIS instrument offers significant economic and technical advantages to customers. However, the TIGRIS instrument will be more expensive for customers to purchase or lease than our existing semi-automated instrument systems. The comparatively higher cost of this new instrument makes it difficult to accurately predict market demand. Because the commercial launch of the TIGRIS instrument is currently underway for use with our APTIMA Combo 2 assay, we do not have a history of TIGRIS instrument sales or leases on which to accurately base predictions of market demand.

Additionally, diagnostic instruments as innovative and complex as the TIGRIS instrument may require frequent service during the period of their initial introduction. We expect to bear the expense of such service costs for most customers. We do not have a history of providing service for TIGRIS instruments and our service costs will depend upon the ultimate reliability of the instrument in the field.

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

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

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

we may in the future compete with bioMérieux and these other licensees for sales of products incorporating our technology. Our competitors may be in a stronger position to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners than we are.

While our current products incorporate end-point detection methods, 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 with respect to such assays and instrumentation then we are.

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

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Chiron, with whom we have entered into 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 bioMeriuex). 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 to ultimately 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 accurately predict 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 46% of our total revenues for the six months ended June 30, 2004 and 42% of our total revenues for 2003. Our blood screening collaboration with Chiron is largely dependent on two large customers in the United States, The American Red Cross and America s Blood Centers, although we did not receive any revenues directly from those entities. Chiron was our only customer that accounted for greater than 10% of our total revenues for the six months ended June 30, 2004. In addition, Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings and various state and city public health agencies accounted for an aggregate of 18% of our total revenues for the six months ended June 30, 2004 and 21% of our total revenues for 2003. Although state and city public health agencies are legally independent of each other, they tend to act similarly with respect to their product purchasing decisions. We anticipate that our operating results will continue to depend to a significant extent upon revenues from a small number of customers. The loss of any of our key customers, or a significant reduction in sales to those customers, could significantly reduce our revenues.

The 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 184 United States patents and 160 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. In addition, all of our existing patents will expire by May 1, 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

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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 similar products and services 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.

We have been involved in a number of patent disputes with third parties, a number of which remain unresolved. Most recently, in February 2004, we filed a patent infringement action in the United States District Court for the Southern District of California alleging that Bayer s bDNA nucleic acid tests for HIV and HCV infringe certain of our patents. In addition, 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. We are also in litigation with Vysis, Inc. regarding the validity of a Vysis patent that Vysis asserts covers the target capture technology that we employ in some of our amplified NAT assays.

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.

The adoption of the Financial Accounting Standards Board SFAS No. 142, Goodwill and Other Intangible Assets as of January 1, 2002 could adversely affect our future results of operations and financial position.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 142, Goodwill and Other Intangible Assets, which we adopted effective on January 1, 2002. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subject to annual impairment tests in accordance with the Statement. As of June 30, 2004, we had goodwill and

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intangible assets valued at approximately $49.5 million, including $24.7 million of capitalized software relating to the TIGRIS instrument, which we began amortizing during the second quarter of 2004, and $6.2 million of capitalized patents and purchased intangibles that have been included in Other assets on the face of our balance sheet. At December 31, 2003, we performed our annual impairment tests of goodwill and indefinite lived intangible assets to determine if an impairment charge should be recognized under SFAS No. 142 and determined that there had been no impairments at that time. In the future, we will continue to test for impairment at least annually. These tests may result in a determination that the assets have been impaired. 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 our 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 the 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 any 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.

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 the 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 years, 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,

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

to retain qualified employees, particularly in light of intense competition for qualified scientists and engineers,

to manufacture additional products ourselves or through third parties,

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

to acquire new technologies, products or companies.

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

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

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

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

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 twelve 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 or our instrument products in compliance with regulatory requirements, in sufficient quantities, on a timely basis and at acceptable costs, or fail

to develop new or replacement systems, 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.

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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.

We distribute instrument systems to be used by our customers in performing our diagnostic assays. These instrument systems have a limited life and may become obsolete over time. For example, our MultiProbe instruments that we have placed with our customers are no longer supported by the manufacturer, and new MultiProbe instruments, while available, are not suitable for our customers. In the future, we intend to develop an instrument to replace the MultiProbe for our lower volume customers. We continue to support our current MultiProbe instruments through our own inventories of parts and used instruments. If we are unable to develop or acquire new instrument systems to replace our existing systems as they become obsolete, we may lose assay product sale revenues and our business may suffer.

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

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

In the past, we have had four voluntary recalls. The first product recall occurred in September 1999, when we responded to customer complaints about an increase in the number of our Mycobacterium Tuberculosis Direct, or MTD, assays demonstrating inhibition by 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. 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 voluntary recall occurred in June 2004 for our MTD product. This customer notification by us was due to decreased stability of a reagent in certain kit lots. The problem was identified and rectified through updated raw material specifications. Our products may be subject to additional recalls in the future and we may not be able to

identify and correct the problems leading to recalls in all circumstances.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 14% of our total revenues for the six months ended June 30, 2004 and 13% of our total revenues for all of 2003. Sales by Chiron outside of the United States accounted for 44% of our international revenues for the six months ended June 30, 2004 and 58% of our international revenues for all of 2003. Chiron has responsibility for the international distribution of our blood screening products, which includes sales in France, Australia, Singapore, New Zealand, Italy and other countries. Our sales in France and Japan that were not made through Chiron accounted for 12% and 7%, respectively, of our international sales for the six months ended June 30, 2004 and 16% and 10%, respectively, for all of 2003.

We expect a significant portion of our sales growth, especially with respect to our blood screening products, to come from expansion

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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 screens for HBV, HIV-1 and HCV. Whenever we seek to enter a new international market, we will be dependent on the marketing and sales efforts of our international distributors.

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

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

We sell our products primarily to large reference laboratories, public health laboratories and hospitals. Large reference laboratories and hospitals 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, standard state funding, 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 our 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

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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. Failure to obtain a supplier 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 us and our consolidated subsidiary, Molecular Light Technology Limited, from the University of Wales College of Medicine. If our license with respect to any of these technologies is terminated for any reason, we will not be able to sell products that incorporate the technology. In addition, although our research staff seeks to discover particular nucleic acid sequences for targeted diseases, our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Likewise, our ability to design products that target these diseases may be based on our ability to obtain the necessary rights from third parties who make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT assays may be economically viable. If we are unable to obtain access to new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

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

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

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

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

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

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

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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 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 becomes 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

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customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

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