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 o