GEN PROBE INC
Form 10-Q
November 09, 2004

Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2004

OR

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

Commission File Number 0-21872

GEN-PROBE INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

As of October 31, 2004, there were 49,823,569 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

GEN-PROBE INCORPORATED

TABLE OF CONTENTS
FORM 10-Q

Table of Contents

Item 1. Financial Statements

GEN-PROBE INCORPORATED

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	September 30, 2004 (unaudited)	December 31, 2003
Current assets:		
Cash and cash equivalents	$ 19,346	$ 35,973
Short-term investments	160,737	120,333
Trade accounts receivable, net of allowance for doubtful accounts of $713 and $717 at September 30, 2004 and December 31, 2003, respectively	18,690	15,158
Accounts receivable other	10,836	2,555
Inventories	29,390	13,676
Deferred income taxes	8,789	10,979
Prepaid expenses and other current assets	15,840	10,203
Total current assets	263,628	208,877
Property, plant and equipment, net	70,147	65,478
Capitalized software, net	24,094	24,872
Goodwill	18,621	18,621
Intangible and other assets	23,238	6,893
Total assets	$ 399,728	$ 324,741
Current liabilities:		
Accounts payable	13,950	9,250
Accrued salaries and employee benefits	12,646	11,670
Other accrued expenses	6,403	6,085
Income taxes payable	2,760	6,191
Deferred revenue	9,649	6,681
Total current liabilities	45,408	39,877
Deferred income taxes	7,425	6,850
Deferred revenue	5,167	5,667
Deferred rent	313	323
Minority interest	1,702	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, 49,778,731 and 48,721,560 shares issued and outstanding at September 30,	5	5

2004 and December 31, 2003, respectively		
Additional paid-in capital	239,751	212,586
Deferred compensation	(1,194)	(538)
Accumulated other comprehensive income	573	343
Retained earnings	100,578	57,979
Total stockholders equity	339,713	270,375
Total liabilities and stockholders equity	$ 399,728	$ 324,741

See accompanying notes to consolidated financial statements.

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**
Revenues:				
Product sales	$ 56,447	$ 47,927	$ 164,077	$ 137,846
Collaborative research revenue	5,532	3,737	19,270	9,474
Royalty and license revenue	1,508	617	17,851	1,811
Total revenues	63,487	52,281	201,198	149,131
Operating expenses:				
Cost of product sales	15,272	10,828	42,300	34,802
Research and development	15,646	16,921	49,961	44,576
Marketing and sales	6,568	5,943	19,958	16,490
General and administrative	9,058	5,740	23,817	15,757
Total operating expenses	46,544	39,432	136,036	111,625
Income from operations	16,943	12,849	65,162	37,506
Other income (expense):				
Minority interest	(103)		(282)	
Interest income	855	564	1,881	1,447
Interest expense	(20)	(14)	(33)	(57)
Other income (expense), net	37	55	(99)	121
Total other income (expense)	769	605	1,467	1,511
Income before income taxes	17,712	13,454	66,629	39,017
Income tax expense	6,602	4,604	24,030	13,364
Net income	$ 11,110	$ 8,850	$ 42,599	$ 25,653
Net income per share[(1)]:				
Basic	$ 0.22	$ 0.18	$ 0.86	$ 0.54
Diluted	$ 0.22	$ 0.18	$ 0.83	$ 0.53
Weighted average shares outstanding[(1)]:				
Basic	49,654	47,987	49,284	47,745
Diluted	51,516	49,974	51,302	48,697

(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.

Table of Contents

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2004	**2003**
Operating activities		
Net income	$ 42,599	$ 25,653
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,988	11,780
Stock compensation charges	1,051	
Loss on disposal of property and equipment	58	75
Deferred rent	(10)	(1)
Stock option income tax benefits	9,639	
Deferred revenue	2,468	481
Deferred income taxes	2,755	148
Minority interest	(27)	
Changes in assets and liabilities:		
Accounts receivable	(5,775)	(2,151)
Inventories	(15,710)	132
Prepaid expenses and other current assets	(5,637)	(5,411)
Accounts payable	4,694	(448)
Accrued salaries and employee benefits	976	959
Other accrued expenses	(291)	(1,261)
Income taxes payable	(3,393)	2,290
Net cash provided by operating activities	46,385	32,246
Investing activities		
Proceeds from sales and maturities of short-term investments	148,444	30,456
Purchases of short-term investments	(188,644)	(64,033)
Purchases of property, plant and equipment	(15,572)	(8,363)
Cash paid for acquisition of Molecular Light Technology shares, net of cash acquired	(376)	(5,941)
Cash paid for Vysis license fee	(22,500)	
Capitalization of software development costs	(270)	(1,553)
Capitalization of patent costs	(410)	(466)
Other assets	(182)	(115)
Net cash used in investing activities	(79,510)	(50,015)
Financing activities		
Proceeds from issuance of common stock	15,819	12,348
Net cash provided by financing activities	15,819	12,348
Effect of exchange rate changes on cash	679	
Net increase (decrease) in cash and cash equivalents	(16,627)	(5,421)
Cash and cash equivalents at the beginning of the period	35,973	43,118
Cash and cash equivalents at the end of the period	19,346	37,697
Supplemental disclosure of cash flow information:		
Cash paid (received) for:		

Interest	$ 33	$ 44
Income taxes	$ 15,692	$ 10,983

See accompanying notes to consolidated financial statements.

Table of Contents

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 September 30, 2004, and for the three and nine month periods ended September 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 nine months ended September 30, 2004 included three more business days compared to the same periods in the prior year.

Note 3 Summary of significant accounting policies

Recent Accounting Pronouncement

During March 2004, the Financial Accounting Standards Board (FASB) issued an exposure draft of a new standard entitled Share Based Payment, which would amend Statement of Accounting Standards (SFAS) No. 123, Accounting for Stock Based Compensation, and SFAS No. 95, Statement of Cash Flows . Among other items, the new standard would require the expensing, in the financial statements, of stock options issued by the Company. The new standard, as proposed, would be effective for periods beginning after June 15, 2005.

Throughout most of 2004, the FASB has continued to deliberate on different aspects of a new standard, and currently expects to issue a final standard in the fourth quarter 2004. Although the Company has not yet completed an analysis to quantify the exact impact the new standard will have on its future financial performance, the disclosures in Note 4 provide detail as to the Company s financial performance as if the Company had applied the fair value based method and recognition provisions of SFAS No. 123 to stock-based employee compensation to the current reporting periods.

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.

In August 2004, the Company paid $376,000 plus accrued interest, in cash, to acquire an additional 3.42% of the outstanding shares of Molecular Light Technology Limited (MLT), a privately held company located in Cardiff, Wales, giving the Company a total ownership of 86% as of September 30, 2004.

Table of Contents

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, MLT 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

The Company has recorded an option-related third quarter non-cash compensation charge of $0.7 million related to the departure of a former executive.

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

Pro forma information regarding net income is required to be disclosed in interim financial statements by SFAS No. 148, and has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method of SFAS No. 123. The fair value for 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 September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**
Risk free interest rate	3.15%	2.86%	3.17%	2.76%
Dividend yield	0%	0%	0%	0%
Volatility factor	62%	47%	63%	48%
Expected life (in years)	4	4	4	4
Resulting average fair value	$18.28	$11.39	$18.82	$10.48

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

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income:				
As reported	$ 11,110	$ 8,850	$ 42,599	$ 25,653
Stock-based employee compensation expense included in reported net income, net of related tax effects	491		547	
Total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(2,870)	(946)	(7,151)	(1,414)
Pro forma net income	$ 8,731	$ 7,904	$ 35,995	$ 24,239
Net income per share:				
As reported				
Basic	$ 0.22	$ 0.18	$ 0.86	$ 0.54
Diluted	$ 0.22	$ 0.18	$ 0.83	$ 0.53
Pro forma				
Basic	$ 0.18	$ 0.16	$ 0.73	$ 0.51
Diluted	$ 0.17	$ 0.16	$ 0.70	$ 0.50

The pro forma effects on net income for the three and nine month periods ended September 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.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$ 11,110	$ 8,850	$ 42,599	$ 25,653
Weighted average shares outstanding				
Basic	49,654	47,987	49,284	47,745
Effect of dilutive common stock options outstanding	1,862	1,987	2,018	952
Weighted average shares outstanding				
Diluted	51,516	49,974	51,302	48,697
Net income per share:				
Basic	$ 0.22	$ 0.18	$ 0.86	$ 0.54
Diluted	$ 0.22	$ 0.18	$ 0.83	$ 0.53

Dilutive securities include options to purchase common stock subject to vesting and unvested restricted stock. Potentially dilutive securities totaling 262,755 and 1,481,758 for the three months ended September 30, 2004 and 2003, and 262,755 and 1,677,626 shares for the nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$ 11,110	$ 8,850	$ 42,599	$ 25,653
Foreign currency translation adjustment	(231)		273	
Change in unrealized gain (loss) on investments	330	(36)	(43)	170
Comprehensive income	$ 11,209	$ 8,814	$ 42,829	$ 25,823

Note 7 Intangible assets by asset class and related accumulated amortization

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

	September 30, 2004			December 31, 2003		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	$ 25,142	$ 1,048	$ 24,094	$ 24,872	$	$ 24,872
Patents	15,174	13,806	1,368	14,764	13,073	1,691
Purchased intangibles	33,636	31,910	1,726	33,636	31,658	1,978
License fees	20,026	160	19,866	3,000	36	2,964
Total	$ 93,978	$ 46,924	$ 47,054	$ 76,272	$ 44,767	$ 31,505
Intangible assets not subject to amortization:						
Goodwill	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621

Table of Contents

In September 2004, the Company entered into a Settlement Agreement and an Amendment to its Nonexclusive License Agreement with Vysis under which the Company has withdrawn its patent litigation against Vysis Inc. (Vysis) and agreed to pay Vysis an aggregate of $22.5 million. This aggregate amount includes $20.5 million for a fully paid up license to eliminate all future royalty obligations of the Company to Vysis under the Collins patent covered by the license, and $2.0 million for a fully paid-up, royalty-free license in additional fields covered by the Collins patent. Chiron Corporation (Chiron), the Company s blood screening partner, has reimbursed the Company $5.5 million of this amount (in October 2004), commensurate with its obligation to reimburse the Company a portion of the royalties paid by the Company to Vysis on blood screening products, resulting in a $17.0 million net intangible asset, which will be amortized to cost of goods sold on a straight-line basis over 135 months.

Note 8 Inventories

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

	September 30, 2004	December 31, 2003
Raw materials	$ 6,604	$ 5,874
Work in progress	10,829	3,118
Finished goods	11,957	4,684
	$ 29,390	$ 13,676

Note 9 Income taxes

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

On October 4, 2004, President Bush signed into Law the Working Families Tax Relief Act of 2004 which extended the expiration date of the United States research tax credit retroactively from after June 30, 2004 through December 31, 2005. Under paragraph 20 of APB 28, any immediate impact as a result of a change in tax law in this case, reinstatement of the credit should be recognized in the interim period in which the law change is enacted. Accordingly, because the credit was reinstated after September 30, 2004, any catch-up adjustment will be recognized when the annual estimated tax rate is remeasured during the Company s fourth quarter. Because the Company has not been permitted to claim a benefit for twelve months of its research and development credit in its full-year estimated tax rate for purposes of calculating its third quarter tax provision, the Company s effective tax rate of approximately 37% during the three months ended September 30, 2004 would have been approximately 36% if the credit had been reinstated earlier.

Tax benefits of $9.6 million in the nine month period ended September 30, 2004 related to employee stock options and stock purchase plans were credited to stockholders equity. The Company did not record any tax benefits in the same period of the prior year.

Note 10 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.

Table of Contents

Common stock

During the three and nine months ended September 30, 2004, 140,434 and 950,081 options, respectively, to purchase shares of the Company s common stock were exercised by Gen-Probe employees at a weighted average exercise price of $15.62 and $13.61, respectively. The Company also issued 856 and 3,660 shares of common stock at fair market value during the three and nine months ended September 30, 2004, to members of the Board of Directors as partial consideration for services rendered, resulting in an expense totaling $34,129 and $140,663, respectively, which was equal to the fair market value on the date of grants. Further, employees purchased 46,713 and 103,430 shares of the Company s common stock at an average purchase price of $29.03 and $27.87 per share, respectively, during the three and nine months ended September 30, 2004, pursuant to the Company s ESPP.

Note 11 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 the on-sale doctrine. Enzo has appealed the summary judgment to the United States Court of Appeals for the Federal Circuit. On September 30, 2004, the defendants filed a joint motion to dismiss Enzo s appeal for lack of subject matter jurisdiction on the ground that counterclaims relating to enforceability of the 659 patent based on inequitable conduct had not been adjudicated and a final judgment had not been entered by the Court. Enzo has opposed the motion to dismiss, which remains pending. 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, Inc., now a wholly-owned subsidiary of Abbott Laboratories, seeking a declaratory judgment that the Company s products were not covered by a Vysis patent, sometimes referred to as the Collins 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 judgment 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

Table of Contents

denial, on July 14, 2004, the District Court dismissed the action with prejudice. On August 20, 2004, the Company filed a petition for review by the United States Supreme Court of the lower court s decision. In September 2004, the Company entered into a Settlement Agreement and an Amendment to Nonexclusive License Agreement with Vysis under which the Company has withdrawn its patent litigation against Vysis and agreed to pay Vysis an aggregate of $22.5 million. This amount includes $20.5 million for a fully paid up license to eliminate all future royalty obligations of the Company to Vysis under the Collins patent covered by the license, and $2.0 million for a fully paid-up, royalty-free license in additional fields under the Collins patent. Chiron, the Company s blood screening partner, has reimbursed the Company $5.5 million of this amount, commensurate with its obligation to reimburse the Company a portion of the royalties paid by the Company to Vysis on blood screening products. The Company s petition for review by the United States Supreme Court was dismissed at the Company s request on October 14, 2004.

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. 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 hearing on the matter began on September 13, 2004 and closing arguments were concluded on November 3, 2004. In accordance with the underlying agreement, the arbitrator has 30 days to render an opinion following the conclusion of certain pending motions. 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 September 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 year ended December 31, 2003.

Table of Contents

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. As a publicly traded company, we have achieved strong growth in both revenues and earnings due principally to the success of our blood screening products which are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, and hepatitis C virus, or HCV. 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 nine months ended September 30, 2004, we achieved strong financial results. Net income for the nine month period ended September 30, 2004 was $42.6 million ($0.83 per diluted share), compared to $25.7 million ($0.53 per diluted share) in the same period of the prior year, an increase of 66%. Total revenues for the nine month period ended September 30, 2004 were $201.2 million, compared to $149.1 million in the same period of the prior year, an increase of 35%. Product sales for the nine month period ended September 30, 2004 were $164.1 million, compared to $137.8 million in the same period of the prior year, an increase of 19%. During the nine months ended September 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

In September 2004, we entered into a Settlement Agreement and an Amendment to our Nonexclusive License Agreement with Vysis under which the Company has withdrawn its patent litigation against Vysis and agreed to pay Vysis an aggregate of $22.5 million. This amount includes $20.5 million for a fully paid up license to eliminate all future royalty obligations of the Company to Vysis under the Collins patent covered by the license, and $2.0 million for a fully paid-up, royalty-free license in additional fields under the Collins patent. The license now covers current and future products in the field of infectious diseases as well as potential products in all other fields, such as our investigational PCA3 prostate cancer test. Chiron has reimbursed us $5.5 million of the $20.5 million allocated to the cost of the fully paid-up license for the current field, commensurate with its obligation to reimburse the Company a portion of the royalties paid by the Company to Vysis on blood screening products. During the fourth quarter 2004, we will begin to amortize our share of the payment to cost of goods sold over the patent s remaining economic life of 135 months.

In September 2004, we signed non-exclusive licensing agreements with bioMérieux and its affiliates that provide bioMérieux options to access our ribosomal RNA technologies for certain uses, and that give us access to bioMérieux s intellectual property for detecting genetic mutations that predispose people to blood clotting disorders. Under the terms of the agreements, bioMérieux paid us $0.25 million for limited non-exclusive research licenses and options to develop products for certain targets using our patented ribosomal RNA technologies. These options may be exercised by bioMérieux for an aggregate $4.5 million payment to us in January 2005. BioMérieux may also acquire rights to develop products for other targets by paying us up to an additional $3.0 million by the end of 2006. The amount of revenue that we record in 2005 and 2006 will depend on the number of targets, if any, selected by bioMérieux. Under the licenses, we will also receive royalties on the sale of any products developed using our intellectual property.

BioMérieux also has terminated its license agreements with us relating to the development of assays for bioMérieux s VIDAS instrument. Further, we have obtained from bioMérieux a non-exclusive, worldwide license to

Table of Contents

use bioMérieux s intellectual property to develop tests that detect mutations in the genes that code for factor V and prothrombin, proteins that control the blood clotting process. We will also pay bioMérieux royalties on the sale of any products developed using bioMérieux s intellectual property. In connection with the VIDAS termination and the license of factor V and prothrombin rights, the Company has recorded net revenue of $0.1 million.

We submitted a Biologics License Application, or BLA, for the Procleix Ultrio (HIV-1/HCV/HBV) assay to the U.S. Food and Drug Administration, or FDA, during the third quarter 2004. We intend to seek approval to run the test on both the semi-automated Procleix system and on the fully automated TIGRIS system. We also submitted a regulatory application to European officials to run the Procleix Ultrio assay on the fully automated TIGRIS instrument. The assay is already approved in Europe to run on our semi-automated instrument platform.

The pivotal clinical trial of the WNV assay is substantially complete, and we expect to file a BLA for the assay in the first quarter 2005. So far this mosquito season, the assay has intercepted approximately 250 WNV-infected blood donations through ongoing national screening under an Investigational New Drug, or IND. In addition, the high-throughput TIGRIS instrument was used by several blood centers to screen both individual donor and pooled blood donations for WNV.

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 recorded during the three months ended March 31, 2004. During January 2004, the Procleix Ultrio assay, running on our semi-automated instrument system, received its Community European, or CE, mark, which permitted Chiron to launch the product in the European Economic Area.

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 nine months ended September 30, 2004, product sales, collaborative research revenues, and royalty and license revenues equaled 81%, 10% and 9%, respectively, of our total revenues of $201.2 million. For the same period in the prior year, product sales, collaborative research revenues, and royalty and license revenues, equaled 92%, 7% and 1%, respectively, of our total revenues of $149.1 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 nine months ended September 30, 2004, we shipped approximately 16.2 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

Table of Contents

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 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 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 nine month periods ended September 30, 2004 and 2003, we recognized $1.8 million and $3.7 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. In September 2004, we filed a BLA with the FDA for this assay. We have also developed a NAT assay to detect WNV, which is currently being used in clinical trials under an IND application. We expect to receive further reimbursement for certain costs incurred during the development of the Procleix Ultrio and WNV assays from Chiron and separately from the National Heart, Lung, and Blood Institute, a part of the NIH.

We have recorded revenues related to use of our blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue, because price restrictions applied to these products prior to FDA license approval in the United States and similar approvals in foreign countries. For the nine months ended September 30, 2004, we recognized $13.7 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 September 30, 2004, the Company had billed all monies remaining under this contract.

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

Table of Contents

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 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 nine month periods ended September 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 charged to inventory 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

Table of Contents

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 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.

Table of Contents

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 September 30, 2004, capitalized software development costs related to our TIGRIS instrument totaled $24.1 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 and filed a BLA with the FDA for this assay in September 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 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 nine month periods ended September 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 September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**
Total revenues	100%	100%	100%	100%
Product sales	89%	92%	81%	92%
Collaborative research revenue	9%	7%	10%	7%
Royalty and license revenue	2%	1%	9%	1%
Operating expenses:				
Cost of product sales	24%	21%	21%	23%
Research and development	25%	32%	25%	30%
Marketing and sales	10%	11%	10%	11%
General and administrative	14%	11%	12%	11%
Total operating expenses	73%	75%	68%	75%
Income from operations	27%	25%	32%	25%

Total other income (expense)	1%	1%	1%	1%
Income before income taxes	28%	26%	33%	26%
Income tax expense	10%	9%	12%	9%
Net income	18%	17%	21%	17%

Table of Contents

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

Product sales

Product sales increased $8.5 million, or 18%, to $56.4 million during the three months ended September 30, 2004, from $47.9 million in the same period of the prior year. The increase was primarily the result of a $4.4 million increase in worldwide commercial sales of our Procleix blood screening products, a $3.8 million increase in STD product sales, primarily APTIMA, and a $0.3 million increase in sales of other diagnostic products. Procleix blood screening product sales represented $24.2 million, or 43% of product sales, for the three months ended September 30, 2004, compared to $19.8 million, or 41% of product sales, for the three months ended September 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 $1.8 million, or 48%, to $5.5 million during the three months ended September 30, 2004, from $3.7 million in the same period of the prior year. The increase was primarily the result of a $3.0 million increase in firm support commitment payments in connection with the WNV tests provided to United States customers through our collaboration with Chiron, partially offset by a $1.1 million decrease in revenue from the NIH to develop a NAT assay for the detection of WNV, as our funds were expended during July 2004.

Royalty and license revenue

Royalty and license revenue increased $0.9 million to $1.5 million in the three months ended September 30, 2004, from $0.6 in the same period of the prior year. The increase was attributed to a $1.0 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 $4.5 million to $15.3 million, or 27% of product sales in the three months ended September 30, 2004, from $10.8 million, or 23% of product sales, in the same period of the prior year. The $4.5 million increase in cost of sales was principally attributed to the volume increase in product sales, higher allowances for scrap expense and amortization of capitalized software development costs related to our TIGRIS instrument. Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales are also affected by manufacturing efficiencies, allowances for scrap or 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 73% in the three months ended September 30, 2004, from 77% in the same period of the prior year due, in part, to increased sales of lower margin products (including TIGRIS instruments) of $0.8 million and the amortization of capitalized software development costs of $0.6 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 $1.3 million to $15.6 million, or 25% of total revenues, in the three months ended September 30, 2004, from $16.9 million, or 32% of total revenues, in the same period of the prior year. The decrease was primarily the result of a $4.6 million decrease in development lot production, which was partially offset by a $2.1 million increase in expenses resulting from higher staffing levels to

Table of Contents

support product development projects, a $0.5 million increase in outside development research, and a $0.8 million increase in expenses related to clinical trials for blood bank.

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 10% of total revenues, in the three months ended September 30, 2004, from $5.9 million, or 11% of total revenues, in the same period of the prior year. The increased spending principally included a $0.8 million increase in salaries, benefits and other personnel costs in our marketing and sales force to support increases in sales of our clinical diagnostic products, partially offset by a $0.2 million decrease in marketing research and evaluations.

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 $3.4 million to $9.1 million, or 14% of total revenues, in the three months ended September 30, 2004, from $5.7 million, or 11% of total revenues, in the same period of the prior year. The increased spending included a $1.3 million increase in expenses resulting from higher staffing levels, including expenses from our majority owned subsidiary, Molecular Light Technology Limited (acquired in August 2003), a $1.1 million increase in patent and legal related expenses, primarily related to the ongoing Bayer arbitration and a $0.7 million non-cash compensation charge related to the departure of a former executive.

Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $769,000 in the three months ended September 30, 2004 represented a $164,000 increase from the net other income of $605,000 in the same period of the prior year. The increase was due to a $291,000 increase in interest income from our short-term investments, partially offset by an increase in minority interest of $103,000.

Income tax expense

Income tax expense increased to $6.6 million, or 37% of pretax income, in the three months ended September 30, 2004, from $4.6 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% and the expiration of federal research and development credits on June 30, 2004. Although the credits were reinstated in October 2004, we are not permitted to reflect the benefit until the fourth quarter of 2004. Our effective tax rate of approximately 37% during the three months ended September 30, 2004 would have been approximately 36% if the credit had been reinstated earlier.

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

Product sales

Product sales increased $26.3 million, or 19%, to $164.1 million during the nine months ended September 30, 2004, from $137.8 million in the same period of the prior year. The increase was primarily the result of a $14.9 million increase in worldwide commercial sales of our Procleix blood screening products, a $9.3 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 $69.8 million, or 43% of product sales, for the nine months ended September 30, 2004, compared to $54.9 million, or 40% of product sales, for the nine months ended September 30, 2003.

Table of Contents

Collaborative research revenue

Collaborative research revenue increased $9.8 million, or 103%, to $19.3 million during the nine months ended September 30, 2004, from $9.5 million in the same period of the prior year. The increase was primarily the result of a $12.2 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 $1.8 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay and a $0.5 million decrease in revenue from the NIH as our funding was completed during July 2004.

Royalty and license revenue

Royalty and license revenue increased $16.1 million to $17.9 million in the nine months ended September 30, 2004, from $1.8 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 we began clinical trial testing in the United States of the Procleix Ultrio assay on the fully automated TIGRIS instrument. Additionally, we recognized $2.5 million in net license income from Bayer during the nine months ended September 30, 2004 for the licensing of rights to certain patented technology.

Cost of product sales

Cost of product sales increased $7.5 million to $42.3 million, or 26% of product sales, in the nine months ended September 30, 2004, from $34.8 million, or 25% of product sales, in the same period of the prior year. The $7.5 million increase in cost of sales was principally attributed to the volume increase in product sales, higher allowances for scrap expense and the amortization of capitalized software development costs.

Our gross profit margin on product sales decreased to 74% in the nine months ended September 30, 2004, from 75% in the same period of the prior year. The decrease was primarily the result of higher allowances for scrap expense of $2.7 million, a sales mix change toward lower margin products (including TIGRIS instruments) of $1.5 million and the amortization of capitalized software development costs of $1.0 million, partially offset by lower unit costs on sales volume increases. Additionally, our margin has benefited from certain manufacturing costs absorbed by research and development for the production of pre-commercial development lots.

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 $5.4 million to $50.0 million, or 25% of total revenues, in the nine months ended September 30, 2004, from $44.6 million, or 30% of total revenues, in the same period of the prior year. The increased spending was primarily the result of a $7.0 million increase in expenses resulting from higher staffing levels to support product development projects, a $2.7 million increase in expenses related to clinical trials for blood screening products, and a $1.2 million increase in research and development expenses from our subsidiary, Molecular Light Technology Limited (acquired in August 2003). These increases were partially offset by a $5.5 million decrease in inventory used due to lower development lot production and lower per unit costs.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $3.5 million to $20.0 million, or 10% of total revenues, in the nine months ended September 30, 2004, from $16.5 million, or 11% of total revenues, in the same period of the prior year. The increased spending principally included a $2.8 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

Table of Contents

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 $8.0 million to $23.8 million, or 12% of total revenues, in the nine months ended September 30, 2004, from $15.8 million, or 11% of total revenues, in the same period of the prior year. The increased spending included a $4.3 million increase in salaries, benefits and other expenses resulting from higher staffing levels, including expenses from our majority owned subsidiary, Molecular Light Technology Limited (acquired in August 2003), a $2.7 million increase in patent and legal related expenses, primarily related to the ongoing Bayer arbitration and a $0.7 million non-cash compensation charge related to the departure of a former executive.

Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $1,467,000 in the nine months ended September 30, 2004 represented a $44,000 decrease from the net other income of $1,511,000 in the same period of the prior year. The decrease was primarily due to a $282,000 increase in minority interest from our subsidiary, Molecular Light Technology Limited, and a $208,000 increase in realized foreign exchange rate losses from our sales to Canadian customers. These decreases were partially offset by a $434,000 increase in interest income from our short-term investments.

Income tax expense

Income tax expense increased to $24.0 million, or 36% of pretax income, in the nine months ended September 30, 2004, from $13.4 million, or 34% of pretax income, in the same period of the prior year. The increased effective tax rate in 2004 is principally attributed to higher profits taxed at the combined Federal and state statutory tax rate of approximately 41%, and to a lesser extent the third quarter 2004 expiration of Federal research and development 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 September 30, 2004, we had $180.1 million of cash and cash equivalents and short-term investments.

For the nine months ended September 30, 2004, net cash provided by operating activities was $46.4 million, compared to $32.2 million in the same period of the prior year. The increase in net cash during the nine months ended September 30, 2004 was principally the result of net income of $42.6 million, depreciation and amortization of $13.0 million, and a $4.7 million increase in accounts payable, partially offset by a $5.8 million increase in accounts receivable and a $15.7 million increase in inventory.

Our investing activities used cash of $79.5 million for the nine months ended September 30, 2004, compared to $50.0 million in the same period of the prior year. During the nine months ended September 30, 2004, we paid an aggregate of $22.5 million to Vysis, Inc. as a pre-paid license fee to eliminate our future royalty obligations to Vysis, of which Chiron reimbursed us $5.5 million in October 2004.

In addition, our investing activities consisted of purchases, net of proceeds of $40.2 million for short-term investments, and $15.6 million for capital expenditures. Our expenditures for capital additions vary based on the stage and number of ongoing 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

Table of Contents

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 nine months ended September 30, 2004, was the result of $15.8 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 September 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 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 the end of 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. During the nine months ended September 30, 2004, we satisfied this obligation and will begin to bill Chiron for their share of qualifying clinical trial expenses throughout the remainder of the eSAS Ultrio and WNV projects in accordance with our agreement.

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 three year term that commenced in November 2003. As of September 30, 2004, approximately $6.9 million remains to be paid to DiagnoCure pursuant to this obligation during the remainder of this three year term.

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

Table of Contents

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 during the first three quarters 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 amendment to our collaboration agreement with Chiron at the beginning of this year. 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 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 conflicts arise with our distributors or other parties with whom we have a commercial relationship or any of our distributors or these other parties terminates its relationship with us or fails to adequately perform, our product sales will suffer and any such conflicts may lead to legal actions or other outcomes that may have a material adverse effect on our business.

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 35% of our total revenues for the nine months ended September 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

Table of Contents

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. 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 hearing on the matter began on September 13, 2004 and closing arguments were concluded on November 3, 2004. In accordance with the underlying agreement, the arbitrator has 30 days to render an opinion following the conclusion of certain pending motions. 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.

From time to time these and other conflicts or disputes may arise with our distributors or other parties with whom we have a commercial relationship. These conflicts or disputes may lead to legal actions, adverse judgments or other outcomes that may have a material adverse effect on our business, financial condition or results of operations.

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.

Table of Contents

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 a specific instrument to bioMérieux, and have granted bioMérieux an option to access our ribosomal RNA technologies for

certain other instruments, 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

Table of Contents

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.

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 nine months ended September 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 nine months ended September 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 20% of our total revenues for the nine months ended September 30,

Table of Contents

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 199 United States patents and 188 foreign patents, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology and the diagnostic products industry, 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 and the diagnostic products industry. 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 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

Table of Contents

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 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 September 30, 2004, we had goodwill and intangible assets valued at approximately $65.6 million, including $24.1 million of capitalized software relating to the TIGRIS instrument, which we began amortizing during the second quarter of 2004, and $22.9 million of capitalized patents, license fees and purchased intangibles that have been included in Intangible and 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

Table of Contents

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,

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.

Table of Contents

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.

31

Table of Contents

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.

Table of Contents

Sales of our products outside the United States accounted for 14% of our total revenues for the nine months ended September 30, 2004 and 13% of our total revenues for all of 2003. Sales by Chiron outside of the United States accounted for 53% of our international revenues for the nine months ended September 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 11% and 7%, respectively, of our international sales for the nine months ended September 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 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

Table of Contents

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 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,

Table of Contents

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 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, or BLA, from the FDA s Center for Biologic Evaluation and Research. Although we submitted a BLA to the FDA for the Procleix Ultrio blood screening assay in September 2004, there is no guarantee that the FDA will approve such application. 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

Table of Contents

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 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.

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

Table of Contents

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

- divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms,
- limit the right of stockholders to remove directors,
- regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders, and
- authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

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

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

On May 28, 2004, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation to increase our authorized number of shares of common stock from 100,000,000 shares to 200,000,000 shares. The additional shares of common stock may be used for various purposes without further stockholder approval. These purposes may include: effecting additional stock dividends; raising capital; providing equity incentives to employees, officers or directors; establishing strategic relationships with other companies; expanding the company s business or product lines through the acquisition of other businesses or products; and other purposes. Although the increase in the authorized common stock was prompted by business and financial consideration and not by the threat of any hostile takeover attempt (nor is the Board currently aware of any such attempts directed as us), nevertheless, the availability of these shares could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices.

We may not successfully integrate acquired businesses.

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

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

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

Table of Contents

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

the exposure to unknown liabilities;

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

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

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

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

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

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

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, any changes requiring that we record compensation expense in the statement of operations for employee stock options using the fair value method or changes in existing taxation rules related to stock options could have a significant negative effect on our reported results. Several agencies and entities are considering, and the Financial Accounting Standards Board has announced, proposals to change generally accepted accounting principles in the United States that, if implemented, would require us to record charges to earnings for employee stock option grants. This pending requirement would negatively impact our earnings. For example, recording a charge for employee stock options under SFAS No. 123, Accounting for Stock-Based Compensation, would have reduced our net income by $2.9 million and $0.9 million for the three months ended September 30, 2004 and 2003, and $7.2 million and $1.4 million for the nine months ended September 30, 2004 and 2003, respectively.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we plan to implement a new general ledger information system and data warehouse to replace our current systems over the next two years. As a part of this effort, we are rationalizing various legacy systems and upgrading existing hardware and software applications and implementing new data management applications to administer our business information. We may

not be successful in implementing the new system, and transitioning data and other aspects of the process could be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the implementation of this new system or any future systems could increase our expenses and adversely affect our

Table of Contents

ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flow and to otherwise operate our business, which could adversely affect our financial results, stock price and reputation.

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

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

Investor confidence and share value may be adversely impacted if our independent auditors are unable to provide us with the attestation of the adequacy of our internal controls over financial reporting as of December 31, 2004, as required by Section 404 of the Sarbanes-Oxley Act of 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission adopted rules requiring public companies to include a report of management on our internal controls over financial reporting in our annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditors must attest to and report on management s assessment of the effectiveness of our internal controls over financial reporting. This requirement will first apply to our Annual Report on Form 10-K for the fiscal year ending December 31, 2004. How companies should be implementing these new requirements including internal control reforms, if any, to comply with Section 404 s requirements, and how independent auditors will apply these new requirements and test companies internal controls, are subject to uncertainty. Although we are diligently and vigorously reviewing our internal controls over financial reporting to comply with the new Section 404 requirements, if our independent auditors are not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated or reviewed, or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may decline to attest to management s assessment or may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements or sanction or investigation by regulatory authorities, which ultimately could negatively impact the market price of our shares.

Available Information

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

rates along the entire interest rate yield curve would not materially affect the fair value of our financial instruments that are exposed to changes in interest rates.

Table of Contents

We are exposed to foreign exchange risk for expenditures in certain foreign countries, but the total receivables and payables denominated in foreign currencies at September 30, 2004 were not material. We believe that our business operations are not exposed to market risk relating to commodity price risk.

Item 4. Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the quarter ended September 30, 2004.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We are also completing our detailed assessment of our internal controls over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act of 2002. That evaluation has included certain internal control areas in which we have made and are continuing to make changes to improve and enhance controls. The changes made to our internal control over financial reporting during the three months ended September 30, 2004 have not materially affected, nor are they reasonably likely to materially affect, our internal control over financial reporting.

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

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 10 Litigation of the Notes to Condensed Consolidated Financial Statements included in Item 1 of Part I of this report and is incorporated by reference herein. See Notes to Condensed Consolidated Financial Statement Note 11 Litigation. We are also engaged in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. If any of these matters were resolved in a manner unfavorable to us, our business, financial condition and results of operations would be harmed.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On September 10, 2004, our Board of Directors converted prior grants of an aggregate of 40,000 shares of restricted common stock previously issued to Mr. Henry L. Nordhoff, our president and chief executive officer, in August 2003 and June 2004 under The 2003 Incentive Award Plan of Gen-Probe Incorporated, into 40,000 shares of deferred issuance restricted stock awards. The previously issued 40,000 shares of restricted common stock were cancelled in exchange for the 40,000 shares of deferred issuance restricted stock awards, which are subject to the same vesting terms as the prior restricted stock awards. Subject to Mr. Nordhoff s continued service to Gen-Probe as an employee, director or consultant, 20,000 shares subject to the award vest as follows: 10,000 shares will vest on August 15, 2005, 5,000 shares will vest on August 15, 2006 and 5,000 shares will vest on August 15, 2007; the remaining 20,000 shares will vest as follows: 5,000 shares will vest on June 1, 2005, then 1/48th of the remaining shares vest monthly thereafter over the following three years. Subject to vesting in accordance with their terms, the vested deferred issuance restricted stock awards will be issued to Mr. Nordhoff on the earlier of: (a) 20,000 on August 15, 2007 and 20,000 on June 1, 2008; or (b) upon the termination of his employment with us.

Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
September 10, 2004	40,000	*	-0-	-0-

*

Consideration was exchange for cancellation of prior grant of an aggregate of 40,000 shares of restricted common stock.

Item 6. Exhibits

Table of Contents

Exhibits

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(1)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.3(5)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.4(5)	Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)	Specimen common stock certificate.
4.2(2)	Rights Agreement, dated as of September 16, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C.
4.4(3)	First Amendment to Rights Agreement, dated October 9, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC.
4.5(4)	Second Amendment to Rights Agreement, dated November 20, 2003.
10.75	The 2000 Equity Participation Plan Forms of Agreements and Grant Notices.
10.76	The 2002 New Hire Stock Option Plan Form of Agreement and Grant Notice.
10.77	The 2003 Incentive Award Plan Form of Agreement and Grant Notice.
10.78	The 2003 Incentive Award Plan Form of Restricted Stock Award Agreement and Grant Notice.
10.79	Settlement Agreement entered into September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc. *
10.80	Amendment to Nonexclusive License Agreement under Vysis Collins Patents entered into September 17, 2004 by and between Gen-Probe Incorporated and Vysis, Inc. *
10.81	Ribosomal Nucleic Acid License and Option Agreement (for Easy Q Instrument) dated September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux B.V. *
10.81(a)	Guarantee Agreement dated September 30, 2004 by bioMérieux SA, on behalf of its subsidiary bioMérieux, Inc., in favor of Gen-Probe Incorporated.
10.82	Ribosomal Nucleic Acid License and Option Agreement (for GeneXpert Instrument) dated September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux, Inc. *

10.82(a)	Guarantee Agreement dated September 30, 2004, by bioMérieux SA, on behalf of its subsidiary bioMérieux b.v., in favor of Gen-Probe Incorporated.
10.83	Side Letter dated October 1, 2004 by and between Gen-Probe Incorporated, bioMérieux B.V., and bioMérieux, Inc. *
10.84	License Agreement entered into September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux B.V. *
10.85	Vidas Termination Agreement entered into September 30, 2004 by and between Gen-Probe Incorporated and bioMérieux, Inc.*

Table of Contents

Exhibit Number	Description
10.86	Deferred Issuance Restricted Stock Conversion Agreement, Deferred Issuance Award Agreement and Election Agreement between Gen-Probe Incorporated and Henry L. Nordhoff, dated October 8, 2004.
31.1	Certification dated November 9, 2004, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification dated November 9, 2004, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification dated November 9, 2004, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification dated November 9, 2004, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

Filed herewith.

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

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

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

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

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

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

Table of Contents

SIGNATURES

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

DATE: November 9, 2004

By: /s/ Henry L. Nordhoff

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

DATE: November 9, 2004

By: /s/ Herm Rosenman

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