GEN PROBE INC
Form 10-Q
May 05, 2006

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 March 31, 2006

OR

o Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Commission File Number 001-31279

GEN-PROBE INCORPORATED
(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction of incorporation or organization)	**33-0044608** (I.R.S. Employer Identification Number)
10210 Genetic Center Drive **San Diego, CA** (Address of Principal Executive Offices)	**92121** (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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer þ Accelerated Filer o Non-Accelerated Filer o

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

As of April 28, 2006, there were 51,588,546 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

GEN-PROBE INCORPORATED
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,590	$ 32,328
Short-term investments	198,496	187,960
Trade accounts receivable, net of allowance for doubtful accounts of $790 as of March 31, 2006 and December 31, 2005	28,569	31,930
Accounts receivable other	2,742	1,924
Inventories	37,717	36,342
Deferred income taxes	10,574	10,389
Prepaid expenses	7,523	10,768
Other current assets	5,450	4,184
Total current assets	335,661	315,825
Property, plant and equipment, net	118,587	105,190
Capitalized software	20,323	20,952
Goodwill	18,621	18,621
License, manufacturing access fees and other assets	50,545	49,648
Total assets	$ 543,737	$ 510,236
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 13,435	$ 14,029
Accrued salaries and employee benefits	16,624	14,910
Other accrued expenses	4,515	3,264
Income tax payable	12,815	13,192
Deferred revenue	5,429	7,771
Total current liabilities	52,818	53,166
Deferred income taxes	5,124	5,124
Deferred revenue	4,167	4,333
Deferred rent	211	240
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, 51,559,833 and 51,137,541 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	5	5
Additional paid-in capital	295,607	281,907
Deferred compensation		(5,951)
Accumulated other comprehensive (loss) income	(1,370)	(1,231)

Retained earnings		187,175		172,643
Total stockholders equity		481,417		447,373
Total liabilities and stockholders equity	$	543,737	$	510,236

See accompanying notes to consolidated financial statements.

Table of Contents

GEN-PROBE INCORPORATED
CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2006	**2005**
Revenues:		
Product sales	$ 78,528	$ 59,579
Collaborative research revenue	6,885	6,344
Royalty and license revenue	843	2,905
Total revenues	86,256	68,828
Operating expenses:		
Cost of product sales	26,112	15,498
Research and development	19,326	18,683
Marketing and sales	8,862	7,426
General and administrative	10,658	7,191
Total operating expenses	64,958	48,798
Income from operations	21,298	20,030
Total other income, net	1,757	1,081
Income before income taxes	23,055	21,111
Income tax expense	8,523	7,650
Net income	$ 14,532	$ 13,461
Net income per share:		
Basic	$ 0.28	$ 0.27
Diluted	$ 0.27	$ 0.26
Weighted average shares outstanding:		
Basic	51,248	50,282
Diluted	52,865	52,367

Net income for the three months ended March 31, 2006 included stock-based compensation expense that the Company recorded as a result of the adoption of SFAS No. 123(R) on January 1, 2006. For the three months ended March 31, 2006, this expense totaled $4,667,000 before income taxes (after deducting $685,000 that has been capitalized to inventory on the Company s balance sheet) and $3,016,000 net of income taxes for the period. The Company did not record stock-based compensation expense for the three months ended March 31, 2005. As previously disclosed in the notes to the financial statements for the three months ended March 31, 2005, net income including pro forma stock-based compensation expense for this period was $9,588,000. See Note 3 to the financial statements for additional information.

See accompanying notes to consolidated financial statements.

4

Table of Contents

GEN-PROBE INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2006	**2005**
Operating activities		
Net income	$ 14,532	$ 13,461
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,061	5,413
Stock-based compensation charges restricted stock	456	125
Stock-based compensation charges all other	4,667	
Stock option income tax benefits		4,692
Excess tax benefit from employee stock options	(4,394)	
(Gain)/loss on disposal of property and equipment	(21)	39
Changes in assets and liabilities:		
Accounts receivable	2,571	(2,070)
Inventories	(688)	(822)
Prepaid expenses	3,246	(5,359)
Other current assets	(1,320)	(439)
Accounts payable	(601)	5,963
Accrued salaries and employee benefits	1,715	(253)
Other accrued expenses	1,240	(525)
Income tax payable	4,015	2,827
Deferred revenue	(2,507)	2,296
Deferred income taxes	(188)	(465)
Deferred rent	(29)	(10)
Minority interest		(58)
Net cash provided by operating activities	28,755	24,815
Investing activities		
Proceeds from sales and maturities of short-term investments	25,935	20,790
Purchases of short-term investments	(36,742)	(32,900)
Purchases of property, plant and equipment	(17,768)	(10,228)
Capitalization of intangible assets, including license and manufacturing access fees	(1,852)	(1,643)
Other assets	17	(791)
Net cash used in investing activities	(30,410)	(24,772)
Financing activities		
Excess tax benefit from employee stock options	4,394	
Proceeds from issuance of common stock	9,449	6,705
Net cash provided by financing activities	13,843	6,705
Effect of exchange rate changes on cash and cash equivalents	74	86

Net increase in cash and cash equivalents	12,262	6,834
Cash and cash equivalents at the beginning of period	32,328	25,498
Cash and cash equivalents at the end of period	$ 44,590	$ 32,332

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 March 31, 2006, and for the three month periods ended March 31, 2006 and 2005, are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP 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 U.S. GAAP. Interim results are not necessarily indicative of the results that may be reported for any other interim period or for the year ending December 31, 2006.

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, 2005.

As discussed in Notes 2 and 3, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, on January 1, 2006 using the modified prospective transition method. Accordingly, the Company s operating income for the three months ended March 31, 2006 includes approximately $4,667,000 in stock-based employee compensation expense. Since the Company elected to use the modified prospective transition method, results from prior periods have not been restated and do not include a corresponding amount of stock-based compensation.

Note 2 Summary of significant accounting policies

Recent accounting pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued revised Statement No. 123(R) (SFAS No. 123(R)) Share-Based Payment, which requires companies to expense the estimated fair value of employee stock options and similar awards. Pro forma disclosure is no longer an alternative. In March 2005, the Securities and Exchange Commission (SEC) released SEC Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment, which provides the SEC staff s position regarding the valuation of share-based payment arrangements for public companies. In April 2005, the SEC adopted a rule that effectively required the Company to implement SFAS No. 123(R) beginning on January 1, 2006.

Under SFAS No. 123(R), stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period. The Company has no awards with market or performance conditions. The Company adopted the provisions of SFAS No. 123(R) on January 1, 2006 using a modified prospective transition method, which provides for certain changes to the method for valuing stock-based compensation. Under the modified prospective transition method, prior periods are not revised for comparative purposes. The valuation provisions of SFAS No. 123(R) apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123).

Contingencies

Contingent gains are not recorded in the Company s financial statements since this accounting treatment could result in the recognition of gains that might never be realized. Contingent losses are only recorded in the Company s financial statements if it is probable that a loss will result from a contingency and the amount can be reasonably estimated.

Principles of consolidation

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

In May 2005, the Company paid $1,539,000 plus accrued interest, in cash, to acquire the remaining outstanding shares of MLT, giving the Company 100% ownership. Prior to purchasing this remaining interest in MLT, the Company had reflected minority

Table of Contents

interest on the balance sheet. This minority interest has since been eliminated and all subsequent earnings (losses) of this subsidiary are fully consolidated into the Company s consolidated financial statements.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP 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, the valuation of stock-based compensation, the valuation of inventories and long-lived assets, including capitalized software, manufacturing and license fees, and income taxes. Actual results could differ from those estimates.

Foreign currencies

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

Note 3 Stock-based compensation

Valuation and amortization method

Upon adoption of SFAS No. 123(R), the Company elected to value its stock-based payment awards granted beginning in 2006 using the Black-Scholes option-pricing model, which was previously used for its pro forma information required under SFAS No. 123. Prior to the adoption of SFAS No. 123(R), compensation cost was amortized over the vesting period using an accelerated graded method in accordance with FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans. Effective January 1, 2006, in conjunction with the adoption of SFAS No. 123(R), the Company now amortizes all new grants as expense on a straight-line basis over the vesting period. Also, certain of these costs are capitalized into inventory on the Company s balance sheet, and generally will be recognized as an expense when the related products are sold. The Company s unamortized compensation expense, before income taxes, related to outstanding unvested stock-based awards was approximately as follows (in thousands):

Awards	Weighted Average Remaining Expense Life (Years)	March 31,2006
Options	1.7	$ 25,360,000
ESPP	0.2	268,000
Restricted stock	1.8	4,156,000
Deferred issuance restricted stock	1.3	1,344,000
		$ 31,128,000

The Company will incur additional expense during 2006 related to new awards granted throughout the remainder of 2006 that cannot yet be quantified. Of the $4,667,000 in stock-based compensation recognized in the first quarter of 2006, approximately $4,367,000 related to awards granted prior to January 1, 2006 and $300,000 related to awards granted during the first quarter of 2006.

At March 31, 2006, we had 152,953 non-vested restricted stock and deferred issuance restricted stock awards that had a weighted average grant date fair value of $41.79. The fair value of the deferred issuance restricted stock vested during the first quarter of 2006 was approximately $52,000.

Expected term

The expected term of stock options granted represents the period of time that they are expected to be outstanding. Due to the Company s relatively short exercise history (commencing in May 2003), the expected term of options granted is now estimated by using the Section 16 Insider reported data from a select group of peer companies. Prior to the second quarter of 2005, the Company believed the expected term approximated the vesting period. Adopting this change has resulted in an increase in the Company s weighted average expected term assumption from 4.0 years in the three months ended March 31, 2005 to 5.4 years in the three months ended March 31, 2006.

Table of Contents

Expected volatility

During 2005, in preparation for the adoption of SFAS No. 123(R), the Company changed its method of estimating the expected volatility associated with stock option grants. Historically, the Company relied exclusively on the historical stock price changes (using daily pricing) and has since determined that a more appropriate estimate is obtained by taking an average of the historical stock price changes (using daily pricing) and the implied volatility on its traded options, consistent with SFAS No. 123(R) and SAB 107. Adopting this change has resulted in a decrease in the Company s weighted average volatility assumption from 59% in the three months ended March 31, 2005 to 44% in the three months ended March 31, 2006.

Risk-free interest rate

The Company determines the risk-free interest rate that it uses in the Black-Scholes option pricing model based upon a constant U.S Treasury Security with a contractual life that approximates the expected term of the option award.

Dividends

The Company has never paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. Therefore, the Company used an expected dividend yield of zero in the Black-Scholes option pricing model.

Forfeitures

SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company s stock-based compensation expense is based on awards ultimately expected to vest. For the three months ended March 31, 2006, the Company reduced stock-based compensation expense to allow for estimated forfeitures based on historical experience. As described in the SFAS No. 123 pro forma information disclosure in the Company s Annual Report on Form 10-K for the year ended December 31, 2005, the Company previously accounted for forfeitures as they occurred.

Assumptions

The Company used the following assumptions to estimate the fair value of options granted and shares purchased under the Company s Employee Stock Purchase Plan (ESPP) for the three month periods ended March 31, 2006 and 2005.

	Stock Option Plans		**ESPP**	
	2006	**2005**	**2006**	**2005**
Risk-free interest rate	4.4%	3.6%	4.0%	2.6%
Volatility	44%	59%	41%	59%
Dividend yield	0	0	0	0
Expected life (years)	5.4	4.0	0.5	0.5
Resulting average fair value	$ 23.13	$ 23.60	$ 12.52	$ 13.24

Table of Contents

Pro forma information for period prior to adoption of SFAS No. 123(R)

SFAS No. 123(R) requires the Company to present pro forma information for the comparative period prior to the adoption as if it had accounted for all of its stock options granted and issued ESPP shares under the fair value method of SFAS No. 123. The following table illustrates the pro forma information regarding the effect on net income and net income per share if the Company had accounted for stock-based employee compensation under the fair value method of accounting (in thousands, except per share data):

		Three Months Ended March 31, 2005
Net income:		
As reported	$	13,461
Stock-based employee compensation expense included in reported net income, net of related tax effects		54
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects		(3,927)
Pro forma net income	$	9,588
Net income per share:		
As reported		
Basic	$	0.27
Diluted	$	0.26
Pro forma		
Basic	$	0.19
Diluted	$	0.18

Impact of the adoption of SFAS No. 123(R)

The following table summarizes the stock-based compensation expense for stock options and our ESPP that we recorded in our statement of income in accordance with SFAS No. 123(R) for the three months ended March 31, 2006.

		Three Months Ended March 31, 2006
Cost of product sales	$	133
Research and development		1,889
Marketing and sales		793
General and administrative		1,852
Reduction of operating income before income taxes		4,667
Income tax benefit		(1,651)
Reduction of net income	$	3,016
Reduction of net income per share:		

Basic	$	0.06
Diluted	$	0.06

The carrying value of inventory on the Company s balance sheet as of March 31, 2006 includes employee stock-based compensation costs of $685,000. Substantially all of the products sold in the first quarter of 2006 were manufactured in previous periods when the Company did not include employee stock-based compensation expense in its production costs. In future periods, when product manufactured after the adoption of SFAS No. 123(R) is sold or written off, or reserves are required due to shelf-life or obsolescence, the Company will recognize employee stock-based compensation expense in cost of product sales.

Prior to the adoption of SFAS No. 123(R), the Company presented deferred compensation related to 60,000 shares of deferred issuance restricted stock and 112,000 shares of restricted stock as a separate component of stockholders equity. On January 1, 2006, in accordance with the provisions of SFAS No. 123(R), the Company reversed the $5,951,000 balance in deferred compensation as an offset against paid-in capital on its balance sheet.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits for deductions resulting from the exercise of stock options as operating cash flows on its statement of cash flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits for tax deductions in excess of the compensation expense recorded for those options (excess tax benefits) to be classified as financing cash flows.

Table of Contents

Note 4 Short-term investments

The following is a summary of short-term investments as of March 31, 2006 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal securities	$ 195,612	$ 31	$ (1,984)	$ 193,659
Foreign debt securities	4,837			4,837
Total short-term investments	$ 200,449	$ 31	$ (1,984)	$ 198,496

The following table shows the gross unrealized losses and fair values of the Company s investments in individual securities that have been in a *continuous unrealized loss position* deemed to be temporary for less than 12 months and for more than 12 months, aggregated by investment category, as of March 31, 2006 (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Municipal securities	$ 75,923	$ (735)	$ 102,375	$ (1,249)
Foreign debt securities				
Total short-term investments	$ 75,923	$ (735)	$ 102,375	$ (1,249)

Note 5 Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share, SFAS No. 123(R), and SAB No. 98. Basic net income per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options when the combined exercise price, average unamortized fair values and assumed tax benefits upon exercise are greater than the average market price for the Company s common stock from the calculation of diluted net income per share because their effect is anti-dilutive.

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

	Three Months Ended March 31,	
	2006	2005
Net income	$ 14,532	$ 13,461
Weighted average shares outstanding Basic	51,248	50,282
Effect of dilutive common stock options outstanding	1,617	2,085
Weighted average shares outstanding Diluted	52,865	52,367
Net income per share:		
Basic	$ 0.28	$ 0.27
Diluted	$ 0.27	$ 0.26

Dilutive securities include common stock options subject to vesting and unvested shares of restricted stock. Potentially dilutive securities totaling 1,156,782 and 127,500 shares for the three month periods ended March 31, 2006 and 2005, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Table of Contents

Note 6 Comprehensive income

Comprehensive income is defined as the change in equity from transactions and other events and circumstances from non-owner sources. 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 the financial statements of our subsidiaries, and unrealized gains and losses on our available for sale securities.

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

	Three Months Ended March 31,	
	2006	**2005**
Net income	$ 14,532	$ 13,461
Change in unrealized loss on investments	(349)	(825)
Foreign currency translation adjustment	210	190
Other comprehensive loss, net	(139)	(635)
Comprehensive income	$ 14,393	$ 12,826

Note 7 Balance sheet information

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

Inventories

	March 31, 2006	December 31, 2005
Raw materials and supplies	$ 5,180	$ 5,430
Work in process	18,942	17,934
Finished goods	13,595	12,978
	$ 37,717	$ 36,342

Property, plant and equipment

	March 31, 2006	December 31, 2005
Land	$ 9,100	$ 9,100
Building	39,581	39,535
Machinery and equipment	111,774	106,433
Leasehold improvements	16,204	16,301
Furniture and fixtures	10,613	10,346
Construction in-progress	44,112	32,143
Property, plant and equipment (at cost)	231,384	213,858
Less accumulated depreciation and amortization	(112,797)	(108,668)
Property, plant and equipment (net)	$ 118,587	$ 105,190

License, manufacturing access fees and other assets

	March 31, 2006			December 31, 2005		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	$ 25,142	$ 4,819	$ 20,323	$ 25,142	$ 4,190	$ 20,952
Patents	16,074	14,917	1,157	15,822	14,817	1,005
Purchased intangible assets	33,636	32,414	1,222	33,636	32,330	1,306
License, manufacturing and other access fees	50,007	4,341	45,666	48,354	3,517	44,837
Total	$ 124,859	$ 56,491	$ 68,368	$ 122,954	$ 54,854	$ 68,100
Goodwill	$ 26,298	$ 7,677	$ 18,621	$ 26,298	$ 7,677	$ 18,621
Investment in Molecular Profiling Institute, Inc.	$ 2,500	$	$ 2,500	$ 2,500	$	$ 2,500

Table of Contents

In February 2006, pursuant to the terms of the Company s January 2005 license agreement with Corixa Corporation, the Company paid Corixa an access license fee of $1,600,000. The license fee has been recorded as an intangible asset that is being amortized on a straight-line basis to research and development expense over the remaining estimated life of the licensed patents.

Note 8 Income taxes

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

The Company currently estimates its annual effective income tax rate to be approximately 37.0% for 2006, compared to the actual 34.5% effective income tax rate in 2005. The Company expects that it will have sufficient taxable income after stock option related deductions to utilize the majority of its deferred tax assets.

Tax benefits of $4,394,000 and $4,692,000 in the three month periods ended March 31, 2006 and 2005, respectively, related to employee stock options and stock purchase plans, were credited to stockholders equity.

Note 9 Stockholders equity

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

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

The Company adopted the 2000 Equity Participation Plan (the 2000 Plan) in August 2000 that provides for the issuance of up to 4,827,946 shares of common stock for grants under the 2000 Plan. The 2000 Plan provides for the grant of incentive and non-statutory stock options. The exercise price of each option granted under the 2000 Plan must be equal to or greater than the fair market value of the Company s stock on the date of grant. The Board of Directors may determine the terms and vesting of all options; however, in no event will the contractual term exceed 10 years. Generally, options vest 25% or 33% one year from the grant date and 1/48 or 1/36, respectively, each month thereafter until the options are fully vested.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2005	5,953,586	$ 29.53		
Granted	90,450	49.68		
Exercised	(421,892)	22.40		
Cancelled	(61,046)	37.31		

Outstanding at March 31, 2006	5,561,098		30.31	7.6	$	136,791
Exercisable at March 31, 2006	2,843,377	$	23.25	6.7	$	90,054

We define in-the-money options at March 31, 2006 as options that had exercise prices that were lower than the $55.12 market price of our common stock at that date. The aggregate intrinsic value of options outstanding at March 31, 2006 is calculated as the difference between the exercise price of the underlying options and the market price of our common stock for the 5,561,098 shares

Table of Contents

that were in-the-money at that date. There were 2,843,377 in-the-money options exercisable at March 31, 2006. The total intrinsic value of options exercised during the first quarter of 2006 was $12,354,000, determined as of the exercise dates.

A summary of the Company s non-vested stock options at March 31, 2006 and changes during the quarter then ended is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value	Weighted Average Remaining Contractual Life (Years)
Non-vested at December 31, 2005	3,013,593	$ 17.09	
Granted	90,450	23.13	
Vested	(325,406)	13.21	
Forfeited	(60,916)	17.87	
Non-vested at March 31, 2006	2,717,721	$ 17.48	8.6

During the three month periods ended March 31, 2006 and 2005, options to purchase 421,892 and 405,895, shares of the Company s common stock were exercised by Gen-Probe employees at a weighted average exercise price of $22.40 and $16.52, respectively.

Changes in stockholders equity for the three months ended March 31, 2006 were as follows (in thousands):

Balance at December 31, 2005	$ 447,373
Net income	14,532
Other comprehensive loss, net	(139)
Net proceeds from the issuance of common stock	9,449
Purchase of common stock by board members	34
Stock-based compensation expense restricted stock	422
Stock-based compensation expense all other	4,667
Stock-based compensation net capitalized to inventory	685
Tax benefit from the exercise of stock options	4,394
Balance at March 31, 2006	$ 481,417

Note 10 Litigation

The Company is a party to the following litigation and may be involved 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 are resolved in a manner unfavorable to the Company, its business, financial condition and results of operations could be harmed.

Bayer Corporation

Arbitration I

In November 2002, the Company filed a demand for arbitration against Bayer Corporation (Bayer), in the Judicial Arbitration & Mediation Services, Inc., (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 June 1998

collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of human immunodeficiency virus (HIV), hepatitis viruses and other specified viruses, subject to certain conditions. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC was also added as a respondent and counterclaimant.

In June 2005, the arbitrator issued an Interim Opinion and Award. The Interim Opinion and Award determined that the Company is entitled to a co-exclusive right to distribute qualitative Transcription-Mediated Amplification (TMA) assays to detect the hepatitis C virus (HCV) and HIV-1 for the remaining term of the Agreement. Bayer previously held the exclusive rights to market these products. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as the Company requested. As a result of a termination of the agreement, the Company will have the right to develop and market future viral assays

that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. Bayer also will be required to reimburse the Company $2,000,000 for the Company s legal fees and expenses related to the arbitration proceedings. As defined in Note 2 Summary of significant accounting policies (Contingencies), the Company will not record any award for reimbursement of legal fees and expenses until the arbitration has been finalized and the cash has been received. The arbitrator denied Bayer s counterclaim.

In the June 2005 Interim Opinion and Award, the arbitrator also concluded that a brief additional hearing would be required to determine whether a royalty payment would be required as a result of the Company exercising its co-exclusive rights to distribute the qualitative TMA assays for HCV and HIV-1, and, if so, the amount and beneficiary of such royalties. On March 3, 2006, the arbitrator issued his Tentative Award following the additional hearing. The arbitrator concluded that Gen-Probe is licensed under the relevant HIV and HCV patents for qualitative assays during the term of the collaboration agreement and that the Company is not obligated to pay Bayer an initial license fee in connection with the sale of those assays. The arbitrator further concluded that the Company will be required to pay running sales royalties on its sales of the TMA assays for HCV and HIV-1, at rates the Company believes are generally consistent with rates paid by other licensees of the relevant patents. The March 3, 2006 Award is subject to revision by the arbitrator following comments by the parties.

The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within JAMS. There can be no assurances as to the final outcome of the arbitration.

Arbitration II

On October 4, 2005, Bayer filed a separate demand for arbitration against the Company with the JAMS office in San Francisco, California and at the same time filed a civil lawsuit against the Company in Superior Court of Massachusetts for Middlesex County. In both the demand for arbitration and the complaint, Bayer alleges that the Company is developing real-time diagnostic assays for HIV and HCV that are covered by certain patents, without the authorization of the patent owner. The subject patents were issued to Chiron Corporation (now Novartis Vaccines and Diagnostics, Inc. (Novartis)) and licensed non-exclusively to Bayer. On October 17, 2005, the Company removed the state court suit to federal court in Boston. On October 21, 2005, Bayer moved to remand the case to the Massachusetts state court. On October 27, 2005, the Company filed a motion to dismiss Bayer s complaint. Both motions are under submission for decision by the court. In the arbitration, the Company requested the arbitrator in the prior arbitration to consolidate Bayer s October 2005 demand for arbitration with the prior proceeding. The Company s motion to consolidate was granted, over Bayer s objection. The Company has filed a motion for summary disposition in the arbitration, and that motion is set for hearing on June 22, 2006. The Company intends to vigorously defend Bayer s allegations. However, there can be no assurance that these matters will be resolved in the Company s favor.

Patent Litigation

In March 2004 the Company filed a separate patent infringement action against Bayer in the United States District Court for the Southern District of California. This action alleges that Bayer s bDNA nucleic acid tests for HIV and HCV infringe Gen-Probe s U.S. patent no. 5,955,261, entitled Method for Detecting the Presence of Group-Specific Viral mRNA in a Sample, the 261 patent. Bayer has denied the allegations of infringement and alleged that the 261 patent is invalid or unenforceable. On August 10, 2005, the Company subsequently amended its complaint to further allege that Bayer s HIV and HCV bDNA tests also infringe Gen-Probe s U.S. patent no. 5,424,413, entitled Branched Nucleic Acid Probes and Gen-Probe s U.S. patent no. 5,451,503, entitled Method for Use of Branched Nucleic Acid Probes. The final pre-trial conference in this case is scheduled for July 17, 2006.

In August 2005, Gen-Probe filed a second patent infringement action against Bayer, alleging that Bayer s bDNA nucleic acid test for hepatitis B virus (HBV) infringes the 261 patent and further alleging that Bayer s bDNA nucleic acid test for HCV infringes Gen-Probe s U.S. patent no. 5,030,557, entitled Means and Method for Enhancing Nucleic Acid Hybridization Assays.

Effective January 1, 2006 the Company entered into an agreement with the law firm of Latham & Watkins LLP concerning attorney s fees incurred for the patent litigation. The agreement provides that in exchange for a reduction in the law firm s monthly fees, the law firm will receive a contingent interest in any recovery in the litigation. There can be no assurances as to the final outcome of the litigation.

Table of Contents

Note 11 Subsequent event

In April 2006, pursuant to the Company s November 2004 License and Preferred Stock Acquisition Agreement with Qualigen, Inc. and based upon the results of an 18-month technical evaluation study, the Company exercised its option to obtain an exclusive worldwide license to Qualigen technology to develop a novel nucleic acid testing (NAT) instrument based on Qualigen s Food and Drug Administration (FDA) approved FastPack® immunoassay system. If development is successful, the new platform, known as a closed unit-dose assay (CUDA) system would use our NAT technologies to detect microorganisms and genetic mutations at the point of sample collection. As part of the option exercise, the Company paid Qualigen $6,993,000 for the purchase of an aggregate number of shares of Qualigen Series D Convertible Preferred Voting Stock and Series D Convertible Preferred Non-Voting Stock convertible into approximately 19.5% of Qualigen s capital stock, on a fully diluted, as converted to common stock basis. Gen-Probe may also pay Qualigen up to $3,000,000 in license fees based on achievement of development milestones under the license agreement and royalties on any eventual product sales. The Company expects to record this investment on a cost basis, and will review the asset for impairment on an ongoing basis.

Table of Contents

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 can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, intends, estimates, could, should, would, continue, seeks, pro forma or anticipates, or other simila their use in the negative). Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. We assume no obligation to update any forward-looking statements.

The following information should be read in conjunction with our March 31, 2006 consolidated financial statements and related notes thereto included elsewhere in this quarterly report and with our consolidated financial statements and notes thereto for the year ended December 31, 2005 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, 2005. 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, 2005.

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 screening of donated human blood. We also develop and manufacture nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. We have over 23 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 countries throughout the world.

We have achieved strong growth in both revenues and earnings due principally to the success of our blood screening products which are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, and hepatitis C virus, or HCV, and hepatitis B virus, or HBV. Under our collaboration agreement with Novartis Vaccines and Diagnostics, Inc., or Novartis, formerly known as Chiron Corporation, or Chiron, we are responsible for the research, development, regulatory process and manufacturing of our blood screening products, while Novartis is responsible for marketing, sales, distribution and service of those products. Since 2002, we have also experienced strong growth in clinical diagnostics for sexually transmitted diseases, or STDs, due to the success of APTIMA Combo 2, which is used to test for chlamydia and gonorrhea.

Recent Events

Financial Results

Product sales for the first quarter of 2006 were $78.5 million, compared to $59.6 million in the same period of the prior year, an increase of 32%. Total revenues for the first quarter of 2006 were $86.3 million, compared to $68.8 million in the same period of the prior year, an increase of 25%. Net income for the first quarter of 2006 was $14.5 million ($0.27 per diluted share), compared to $13.4 million ($0.26 per diluted share) in the same period of the prior year. Net income in the first quarter of 2006 included $3.0 million ($0.06 per diluted share) in stock-based compensation expense due to the adoption of SFAS No. 123(R).

Licensing

In February 2006, pursuant to the terms of our license agreement with Corixa Corporation, we paid an access license fee of $1.6 million. We recorded the license fee as an intangible asset that is being amortized on a straight-line basis to research and development expense over the underlying life of the patents.

In February 2006, pursuant to the terms of our license agreement with AdnaGen AG, we paid a license fee of $0.75 million. We recorded the license fee as research and development, or R&D, expense, since we have not yet determined technological feasibility and do not currently have alternative future plans to use this technology other than for our prostate cancer development program.

16

Table of Contents

In April 2006, pursuant to our November 2004 License and Preferred Stock Acquisition Agreement with Qualigen, Inc. and based upon the results of an 18-month technical evaluation study, we exercised our option to obtain an exclusive worldwide license to Qualigen technology to develop a novel NAT instrument based on Qualigen s Food and Drug Administration, or FDA, approved FastPack immunoassay system. If development is successful, the new platform, known as a closed unit-dose assay, or CUDA, system would use our NAT technologies to detect microorganisms and genetic mutations at the point of sample collection. As part of the option exercise, we paid Qualigen approximately $7.0 million for the purchase of an aggregate number of shares of Qualigen Series D Convertible Preferred Voting Stock and Series D Convertible Preferred Non-Voting Stock convertible into approximately 19.5% of Qualigen s capital stock, on a fully diluted, as converted to common stock basis. We may also pay Qualigen up to $3.0 million in license fees based on achievement of development milestones under the license agreement and royalties on any eventual product sales.

Product Development

In January 2006, we submitted to the FDA a prior approval supplement for our APTIMA HIV-1 qualitative assay. We expect to launch qualitative HIV-1 and HCV tests for clinical diagnostic use during the third quarter of 2006.

In March 2006, we began shipment to Novartis of FDA approved and labeled Procleix WNV assays for use with the Procleix enhanced semi-automated system, or eSAS. In April 2006, we submitted to the FDA a post-approval supplement to our WNV assay Biologics License Application, or BLA, adding the TIGRIS instrument and we submitted for 510(k) clearance of the TIGRIS instrument for use with the WNV assay at the same time. There can be no assurance that the TIGRIS instrument will receive FDA clearance for use with the WNV assay.

During the quarter ended March 31, 2006, two clinical laboratories began validation of TMA assays for PCA3 and PSA, using our assay specific reagents, or ASRs and general purpose reagents, or GPRs. We expect these laboratories to begin offering these tests to physicians and reporting patient results, employing a PCA3 to PSA ratio, in the second quarter of 2006.

In March 2006, we submitted to the FDA an amendment to our BLA for the Procleix Ultrio assay on eSAS. The Procleix Ultrio assay was developed to simultaneously detect HIV-1, hepatitis C virus and hepatitis B virus in donated blood, plasma, organs and tissues. The assay is approved for commercial blood screening use in many countries outside the United States. We originally submitted the BLA for the Procleix Ultrio assay in September 2004. In October 2005, we received a complete review letter from the FDA setting forth questions regarding our BLA for the Procleix Ultrio assay itself. The BLA amendment submitted in March 2006 responded to questions asked by the FDA in the October 2005 complete review letter.

In October 2005 the FDA also notified us that it considers our TIGRIS instrument not substantially equivalent for blood screening to our already cleared eSAS. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening for use with the Procleix Ultrio assay. We anticipate submitting a new 510(k), and a post-approval BLA supplement, for the TIGRIS instrument for use with the Procleix Ultrio assay following approval of the BLA for the Procleix Ultrio assay on eSAS and following clearance of the 510(k) for TIGRIS for use with the WNV assay. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the Procleix Ultrio assay.

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 performed on our proprietary instruments that serve as the analytical platform for our assays. We recognize as collaborative research revenue payments we receive from Novartis for the products provided under our collaboration agreements with Novartis prior to regulatory approval, and the payments we receive from Novartis, Bayer Corporation, or Bayer, and other collaboration partners 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 first quarter of 2006, product sales, collaborative research revenues and royalty and license revenues equaled 91%, 8% and 1%, respectively, of our total revenues of $86.3 million. For the same period in the prior year, product sales, collaborative research revenues, and royalty and license revenues equaled 87%, 9%, and 4%, respectively, of our total revenues of $68.8 million.

17

Table of Contents

Product sales

Our primary source of revenue is the sale of clinical diagnostic and blood screening products in the United States. Our clinical diagnostic products include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During the first quarter of 2006, we shipped approximately 6.2 million tests for the diagnosis of a wide variety of infectious microorganisms, including those causing STDs, tuberculosis, strep throat, pneumonia and fungal infections. The principal customers for our clinical diagnostics products include large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

Since 1999, we have supplied NAT assays for use in screening blood donations intended for transfusion. Our primary blood screening assay detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments are marketed through our collaboration with Novartis under the Procleix and Ultrio trademarks. We recognize product sales from the manufacture and shipment of tests for screening donated blood at the contractual transfer prices specified in our collaboration agreement with Novartis for sales to blood bank facilities located in countries where our products have obtained governmental approvals. Blood screening product sales are then adjusted monthly corresponding to Novartis payment to us of amounts reflecting our ultimate share of net revenue from sales by Novartis to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Novartis to third parties, less freight, duty and certain other adjustments specified in our agreement with Novartis, multiplied by our share of the net revenue. Our share of net revenues from commercial sales of assays that include a test for HCV is 45.75% under our agreement with Novartis. With respect to commercial sales of blood screening assays under our collaboration with Novartis that do not include a test for HCV, such as the WNV assay, we will receive 50% of net revenues after deduction of appropriate expenses. Our costs related to these products primarily include manufacturing costs.

Collaborative research revenue

We have recorded revenues related to use of our blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue because of price restrictions applied to these products prior to FDA license approval in the United States and similar approvals in foreign countries. For each of the first quarters of 2006 and 2005, we recognized $4.5 million, as collaborative research revenue through our collaboration with Novartis from deliveries of WNV tests on a cost recovery basis. For the first quarters of 2006 and 2005, we recognized $0.6 million and $0.7 million respectively, in reimbursements for expenses incurred for WNV development research as collaborative research revenue. In December 2005, the FDA granted marketing approval for our WNV assay on eSAS to screen donated human blood. The 510(k) clearance of eSAS for use with the WNV assay was granted prior to the assay s approval. In April 2006, we submitted to FDA a post-approval supplement to our WNV assay BLA adding the TIGRIS instrument and we submitted for 510(k) clearance of the TIGRIS instrument for use with the WNV assay at the same time. In the first quarter of 2006, we discontinued recognizing sales of the WNV assay for use on eSAS as collaborative research revenue upon shipment of FDA approved and labeled product.

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

Royalty and license revenue

We recognize non-refundable up-front license fees over the performance period of an agreement or at the time that we have satisfied all substantive performance obligations of an agreement. We also receive milestone payments for successful achievement of contractual development activities. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) we have earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement, (iii) the fees are non-refundable, and (iv) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. Any amounts received

prior to satisfying our revenue recognition criteria are recorded as deferred revenue on our balance sheet.

Table of Contents

Under the strategic alliance agreement with Novartis, we have responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Novartis has responsibility for marketing, distribution and service of the blood screening products worldwide. During 2004, we recognized as royalty and license revenue, a $6.5 million milestone payment from Chiron as we commenced clinical trials of the Procleix Ultrio assay on our TIGRIS instrument in the United States. Under the terms of the agreement, an additional payment of $10.0 million is due to us in the future if we obtain FDA approval of our Procleix Ultrio assay for use on the TIGRIS instrument. There is no guarantee we will achieve this milestone and receive any additional milestone payments under this agreement. In October 2005, the FDA notified us that it considers our TIGRIS instrument not substantially equivalent for blood screening to our already cleared eSAS.

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. Other components of cost of product sales include royalties, warranty costs, instrument and software amortization and allowances for scrap.

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 first quarter of 2005, our manufacturing facilities produced large-scale development lots for WNV and Procleix Ultrio assays. There were no large-scale blood screening development lots produced in the first quarter of 2006. The majority of costs associated with these development lots are classified as research and development expense. The portion of a development lot that is manufactured for commercial sale outside the United States is capitalized to inventory and classified as cost of product sales upon shipment.

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

During the first quarters of 2006 and 2005, the growth in our blood screening revenues was partially driven by sales of TIGRIS instruments to Novartis totaling approximately $3.6 million and $0.8 million, respectively. Under our contract with Novartis, we sell TIGRIS instruments to them at prices that approximate cost. These instrument sales, therefore, negatively impact our gross margin percentage in the periods when they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

Research and development

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

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

R&D expenses include the costs of raw materials, development lots and clinical trial lots of products that we manufacture. These costs are dependent on the status of projects under development and may vary substantially between quarterly or annual reporting periods. We expect to incur additional costs associated with the manufacture of developmental lots and clinical trial lots for our blood screening products and with further development of our TIGRIS instrument as well as for development of assays for PCA3 and human papillomavirus, or HPV. Collaborative research revenues associated with these types of costs have at times been realized in a period later than when the costs

were incurred due to the need for clarification on the extent of reimbursable costs.

Table of Contents

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 U.S. generally accepted accounting principles, or U.S. GAAP. 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 stock-based compensation, 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, which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

We believe there have been no significant changes during the three months ended March 31, 2006 to the items that we disclosed as our critical accounting policies and estimates in Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2005, except for the item discussed below.

Stock-based compensation expense

Effective January 1, 2006, we adopted, using a modified prospective transition method, Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, or SFAS No. 123(R), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including stock options, employee stock purchases related to the Employee Stock Purchase Plan, or ESPP, and restricted stock based on fair values. Our financial statements as of and for the first quarter of fiscal year 2006 reflect the impact of SFAS No. 123(R). In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS No. 123(R). Stock-based compensation expense recognized is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. Stock-based compensation expense recognized in our Consolidated Statement of Income during the first quarter of 2006 included compensation expense for stock-based payment awards granted prior to, but not yet fully vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS No. 123 and compensation expense for the stock-based payment awards granted subsequent to 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). In conjunction with the adoption of SFAS No. 123(R), we elected to attribute the value of stock-based compensation to expense using the straight-line method, whereas prior to adoption we used an accelerated graded method in accordance with Financial Accounting Standards Board Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans. During the first quarter of 2006, stock-based compensation expense related to stock options and employee stock purchases was $4.7 million, before taxes on earnings. During the first quarters of 2006 and 2005, stock-based compensation expense related to restricted stock was $0.4 million and $0.1 million, respectively, which would have been recorded under Accounting Principles Board Opinion No. 25. See Note 3 to the Consolidated Financial Statements for additional information.

Upon adoption of SFAS No. 123(R), we elected to value our stock-based payment awards granted after 2005 using the Black-Scholes option-pricing model, or the Black-Scholes model, which we previously used for the pro forma information required under SFAS No. 123. For additional information, see Note 3 to the Consolidated Financial Statements. The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and our expected stock price volatility over the term of the awards. Our stock options and the option component of the ESPP shares have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

The expected term of stock options granted represents the period of time that they are expected to be outstanding. Due to our relatively short exercise history (commencing in May 2003), the expected term of options granted is now

estimated by using the Section 16 Insider reported data from a select group of peer companies. Prior to the second quarter of 2005, we believed the expected term approximated the vesting period. Adopting this change has resulted in an increase in our weighted average expected term assumption from 4.0 years in the first quarter of 2005 to 5.4 years in the first quarter of 2006. We also changed our method of estimating the expected volatility associated with stock option grants. Historically, we relied exclusively on the historical stock price changes (using daily pricing) and we have since determined that a better estimate is obtained by taking an average of the historical stock price changes (using daily pricing) and the implied volatility on our traded options. Adopting this change has resulted in a decrease in our weighted average volatility assumption from 59% in the first quarter of 2005 to 44% in the first quarter of 2006.

Table of Contents

SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Our stock-based compensation expense is based on awards ultimately expected to vest. For the first quarter of 2006, we reduced stock-based compensation expense to allow for estimated forfeitures based on historical experience. In our pro forma information required under SFAS No. 123 for the periods prior to 2006, we accounted for forfeitures as they occurred. If factors change and we employ different assumptions in the application of SFAS No. 123(R) in future periods, the compensation expense that we record under SFAS No. 123(R) may differ significantly from what we have recorded in the first quarter of 2006.

Results of Operations

	Three Months Ended March 31,		Change	
	2006	2005	Amount	%
	(In millions, except per share data)			
Statement of income:				
Revenues:				
Product sales	$ 78.5	$ 59.6	$ 18.9	32%
Collaborative research revenue	6.9	6.3	0.6	10%
Royalty and license revenue	0.9	2.9	(2.0)	(69%)
Total revenues	86.3	68.8	17.5	25%
Operating expenses:				
Cost of product sales	26.1	15.5	10.6	68%
Research and development	19.3	18.7	0.6	3%
Marketing and sales	8.9	7.4	1.5	20%
General and administrative	10.7	7.2	3.5	49%
Total operating expenses	65.0	48.8	16.2	33%
Income from operations	21.3	20.0	1.3	7%
Total other income, net	1.7	1.1	0.6	55%
Income tax expense	8.5	7.7	0.8	10%
Net income	$ 14.5	$ 13.4	$ 1.1	8%
Net income per share				
Basic	$ 0.28	$ 0.27	$ 0.01	4%
Diluted	$ 0.27	$ 0.26	$ 0.01	4%
Weighted average shares outstanding				
Basic	51.2	50.3		
Diluted	52.9	52.4		

Amounts and percentages in this table and throughout our discussion and

analysis of financial conditions and results of operations may reflect rounding adjustments. Percentages have been rounded to the nearest whole percentage.

Table of Contents

Product sales

Product sales increased 32% to $78.5 million during the first quarter of 2006, from $59.6 million in the first quarter of 2005. The $18.9 million increase was primarily attributed to $8.1 million in higher blood screening sales, $6.8 million in higher APTIMA Combo 2 assay sales, and $5.7 million in higher instrument sales, partially offset by a $1.6 million decrease in PACE product sales. Blood screening sales represented $38.4 million, or 49% of product sales, in the first quarter of 2006, compared to $25.4 million, or 43% of product sales for the first quarter of 2005. The increase in blood screening sales during the first quarter of 2006 was principally attributed to an increase in domestic sales of our WNV assay, increased international Procleix Ultrio assay sales volume and an increase in instrument sales.

We expect increased competitive pressures related to our STD and blood screening products in the future, primarily as a result of the introduction by others of competing products into both the STD and blood screening markets, and continuing pricing pressure in the STD market.

Collaborative research revenue

Collaborative research revenue increased 10% in the first quarter of 2006 from the first quarter of 2005. The $0.6 million increase was primarily the result of a $0.7 million increase in revenue for reimbursement from Millipore Corporation for certain assay development costs and a $0.3 million increase in revenue for shipments of discriminatory HBV, or dHBV, assays and TIGRIS instrument lease revenue from Novartis. These increases were partially offset by a $0.4 million decrease in reimbursements for expenses from Novartis for development research and warehousing fees.

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

Royalty and license revenue

Royalty and license revenue decreased 69% in the first quarter of 2006 from the first quarter of 2005. The $2.0 million decrease was principally attributed to $1.9 million in license fee revenue we recognized from bioMérieux s affiliates during the first quarter of 2005, which was based on the selection of targets pursuant to the terms of our September 2004 agreement with bioMérieux, and a $0.2 million decrease in our share of royalties from Novartis, based upon its agreement with Laboratory Corporation of America for use of Novartis HCV intellectual property for NAT used in screening plasma donations in the United States.

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

Cost of product sales

Cost of product sales increased 68% in the first quarter of 2006 from the first quarter of 2005. The $10.6 million increase was principally attributed to increased sales of TIGRIS instruments and spare parts to Novartis ($4.9 million), higher blood screening product shipments primarily to international markets ($2.6 million), commercial launch of our WNV assay ($1.0 million), higher APTIMA shipments ($1.3 million) and higher instrument warranty costs ($0.8 million).

Our gross profit margin as a percentage of product sales decreased to 67% in the first quarter of 2006, from 74% in the first quarter of 2005. The decrease in gross profit margin percentage was principally attributed to increased sales of lower margin products, including TIGRIS instruments and spare parts, higher international sales of blood screening products, which generally have had lower margin rates than domestic sales, and higher instrument warranty costs.

22

Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales are also affected by manufacturing efficiencies, allowances for scrap or expired materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

We anticipate that requirements for smaller pool sizes or ultimately individual donor testing of blood samples, if and when implemented, could result in lower gross margin percentages, as additional tests would be required to deliver the sample results, unless a corresponding increase in sales price is implemented. We are not able to accurately predict the timing and extent to which our gross margin percentage may be negatively affected as a result of smaller pool sizes or individual donor testing because we do not know the ultimate selling price that Novartis, our distributor, would charge the end user if smaller pool sizes or individual donor testing were implemented. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion has led to lower gross margin percentages.

Research and development

Our R&D expenses include salaries and other personnel-related expenses, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. R&D expenses increased 3% during the first quarter of 2006 from the first quarter of 2005. The $0.6 million increase was primarily due to a $2.0 million increase in stock-based compensation expense and increased spending on outside services ($1.0 million), partially offset by reductions in clinical trials for blood screening products ($0.6 million), and a decrease in WNV and Ultrio development lot production ($1.5 million).

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased 20% during the first quarter of 2006 from the first quarter of 2005. The $1.5 million increase was primarily due to a $0.8 million increase in stock-based compensation expense, a $0.2 million increase in salaries, benefits, commissions and other personnel related costs, together with a $0.2 million increase in spending for professional fees, and $0.2 million in increased spending on conferences.

General and administrative

Our general and administrative, or G&A, expenses include personnel costs for finance, legal, strategic planning and business development, public relations and human resources, as well as professional fees, such as expenses for legal, patents and auditing services. G&A expenses increased 49% during the first quarter of 2006 from the first quarter of 2005. The $3.5 million increase was primarily the result of a $2.0 million increase in stock-based compensation expense, a $0.6 million increase in salaries, benefits and other personnel related expenses, and a $0.9 million increase in professional fees due to higher legal fees associated with the Company s two patent infringement lawsuits against Bayer Corporation.

Total other income, net

Total other income, net, generally consists of investment and interest income offset by interest expense, and other items. The $0.6 million net increase during the first quarter of 2006 from the first quarter of 2005 was primarily due to an increase in interest income resulting from higher average balances of our short-term investments and higher yields on our investment portfolio.

Income tax expense

Income tax expense increased to $8.5 million, or 37.0% of pretax income, in the first quarter of 2006, from $7.7 million or 36.2% of pretax income, in the first quarter of 2005. The increase in our effective tax rate is principally attributed to the expiration of the federal research and development credit on December 31, 2005 and our first quarter of 2006 adoption of SFAS No. 123(R), partially offset by benefits from increases in our tax exempt interest income.

Table of Contents

Liquidity and capital resources
(In thousands)

	March 31, 2006	December 31, 2005
Cash, cash equivalents and short-term investments	$ 243,086	$ 220,288
Working capital	$ 282,843	$ 262,659
Current ratio	6:1	6:1

	Three Months Ended March 31,		
	2006	2005	$ Change
Cash provided by (used in):			
Operating activities	$ 28,755	$ 24,815	$ 3,940
Investing activities	(30,410)	(24,772)	(5,638)
Financing activities	13,843	6,705	7,138
Purchases of property, plant and equipment (included in investing activities above)	$ (17,768)	$ (10,228)	$ (7,540)

Historically, we have financed our operations through cash from operations, cash received from collaborative research agreements, royalty and license fees, and cash from capital contributions. At March 31, 2006, we had $243.1 million of cash and cash equivalents and short-term investments.

The $3.9 million increase in net cash provided by operating activities during the first quarter of 2006 from the first quarter of 2005 was primarily attributable to higher net income (net of non-cash stock-based compensation expense) and improved collections of trade accounts receivable along with a decrease in prepaid expenses due to the timing of instrument purchases and deliveries. These increases in net cash provided by operating activities were partially offset by a decrease in accounts payable growth due to the acceleration of payments to our vendors in December 2004, immediately prior to our implementation of a new Enterprise Resource Planning, or ERP, software system in January 2005.

The $5.6 million increase in net cash used in investing activities during the first quarter of 2006 from the first quarter of 2005 included a $7.5 million increase in capital expenditures, partially offset by a $1.3 million decrease in purchases (net of sales) of short-term investments. Our 2006 growth in capital expenditures was primarily due to the construction of our new building and related telecommunication expenses. Our expenditures for capital additions vary based on the stage of certain development projects and may increase in the future related to the timing of development of new product opportunities and to support expansion of our facilities in connection with those opportunities. We expect capital expenditures in 2006 to approximate 2005 spending.

The $7.1 million increase in net cash provided by financing activities during the first quarter of 2006 from the first quarter of 2005 was principally attributed to a $2.7 million increase in proceeds from the exercise of stock options along with $4.4 million in tax benefits from employee stock options that have been reclassified from operating activities to financing activities in accordance with SFAS No. 123(R) beginning in January 2006. On a going-forward basis, cash from financing activities will continue to be affected by proceeds from the exercise of stock options and receipts from sales of stock under our ESPP. We expect fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock, along with other factors.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2007, 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. As of March 31, 2006, we were in compliance with all covenants.

In July 2004, we commenced construction of an additional building to expand our main San Diego campus. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 190,000 square feet built-out with interior improvements. The additional space that will not initially be built-out will allow for future expansion. The first phase of this project is currently estimated to cost approximately $45.0 million, of which $43.0 million was capitalized to construction in-progress as of March 31, 2006. These costs are being capitalized as incurred and depreciation will commence upon our completion and use of the building, which is planned for the second quarter of 2006.

Table of Contents

We implemented a new ERP system that cost approximately $4.9 million in 2004. We incurred $3.3 million in additional costs during 2005 and expect to incur approximately $1.0 to $2.0 million of costs in 2006 for further enhancements to our ERP system.

Contractual obligations and commercial commitments

Our contractual obligations due to lessors for properties that we lease, as well as amounts due for purchase commitments and collaborative agreements as of March 31, 2006 were as follows (in thousands):

	Total	2006	2007	2008	2009	Thereafter
Operating leases [1]	$ 2,504	$ 1,404	$ 863	$ 167	$ 70	$
Material purchase commitments [2]	23,301	14,757	8,544			
Collaborative commitments [3]	17,454	4,054	2,650	10,000	750	
Total [4]	$ 43,259	$ 20,215	$ 12,057	$ 10,167	$ 820	$

(1) Reflects obligations on facilities under operating leases in place as of March 31, 2006. Future minimum lease payments are included in the table above.

(2) Amounts represent our minimum purchase commitments from two key vendors for TIGRIS instruments and raw materials used in manufacturing. Of the $19.2 million expected to be purchased for TIGRIS instruments in 2006 and 2007, we anticipate that

approximately $13.5 million will be reimbursed by Novartis.

(3) In addition to the minimum payments due under our collaborative agreements, we may be required to pay up to $4.25 million in milestone payments, plus royalties on net sales of any products using specified technology. Further, on April 17, 2006 we exercised our option to develop a point of sample collection NAT instrument, and purchased an equity interest in Qualigen for approximately $7.0 million. We may pay up to an additional $3.0 million based on development milestones, plus royalties on any eventual product sales.

(4) Does not include amounts relating to our obligations under our collaboration

with Novartis, pursuant to which both parties have obligations to each other. We are obligated to manufacture and supply our blood screening assay to Novartis, and Novartis is obligated to purchase all of the quantities of this assay specified on a 90-day demand forecast, due 90 days prior to the date Novartis intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

Additionally, we have long-term liabilities for deferred employee compensation. The payments related to the deferred compensation are not included in the table above since they are dependent upon when certain key employees retire or otherwise leave the Company.

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

We believe that our available cash balances, anticipated cash flows from operations, proceeds from stock option exercises, and available line of credit, will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to covenants restricting our operations. In August 2003, we filed a Form S-3 shelf registration statement with the SEC relating to the possible future sale of up to an aggregate of $150 million of debt or equity securities. To date, we have not raised any funds under this registration statement.

We may from time to time consider the acquisition of businesses and/or technologies complementary to our business. We could require additional equity or debt financing if we were to engage in a material acquisition in the future.

We do not currently have and have never had any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been

established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Table of Contents

Stock Options

Option program description

Our stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and to align stockholder and employee interests. Our primary program consists of a broad-based plan under which stock options are granted to employees and directors. Substantially all of our employees have historically participated in our stock option program.

General option and equity compensation plan information

Summary of Option and Restricted Stock Activity

(Shares in thousands)

	Shares Remaining Available for Future Issuance	Options Outstanding Number of Shares to be Issued Upon Exercise	Weighted Average Exercise Price	Restricted Stock Awards	Director Stock Purchases
December 31, 2004	1,915	6,004	$ 25.03	40	
Grants	(1,363)	1,228	43.82	132	3
Exercises		(890)	17.65		(3)
Cancellations	388	(388)	32.78		
December 31, 2005	940	5,954	$ 29.53	172	
Grants	(91)	90	49.68		1
Exercises		(422)	22.40		(1)
Cancellations	61	(61)	37.31		
March 31, 2006	910	5,561	$ 30.31	172*	

* Includes 60,000 shares of Deferred Issuance Restricted Stock and approximately 112,000 shares of Restricted Stock as of March 31, 2006.

In-the-Money and Out-of-the-Money Option Information

(Shares in thousands)

Exercisable		Unexercisable		Total	
	Wtd. Avg. Exercise		Wtd. Avg. Exercise		Wtd. Avg Exercise

As of March 31, 2006	Shares	Price	Shares	Price	Shares	Price
In-the-Money	2,843	$ 23.25	2,718	$ 37.69	5,561	$ 30.31
Out-of-the Money[1]						
Total Options Outstanding	2,843		2,718		5,561	

(1) Out-of-the-money options are those options with an exercise price equal to or greater than the fair market value of our common stock, $55.12, at the close of business on March 31, 2006.

Table of Contents

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 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately $3.6 million annually. While changes in our interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our statement of income until the investment is sold or if a reduction in fair value is determined to be a permanent impairment.

Foreign Currency Exchange Risk

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

We are exposed to foreign exchange risk for expenditures in certain foreign countries, but the total receivables and payables denominated in foreign currencies as of March 31, 2006 were not material. Under our collaboration agreement with Novartis, a growing portion of blood screening product sales is from western European countries. As a result, our international blood screening product sales are affected by changes in the foreign currency exchange rates of those countries where Novartis business is conducted in Euros or other local currencies. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Based on international blood screening product sales during the first quarter of 2006, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $0.9 million. We believe that our business operations are not exposed to market risk relating to commodity price risk.

Item 4. Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the quarter ended March 31, 2006.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation has included certain internal control areas in which we have made and are continuing to make changes to improve and enhance controls.

There have been no other changes in our internal control over financial reporting during the three months ended March 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 10 Litigation of the Notes to 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 10 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 1A. 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, the timing of milestone payments, or the failure to achieve and receive the same, and the initiation or termination of corporate collaboration agreements. A significant portion of our costs also can vary substantially between quarterly or annual reporting periods. For example, the total amount of research and development costs in a period often depends on the amount of research and development costs we incur in connection with manufacturing developmental lots and clinical trial lots. We incurred substantial costs of manufacturing these lots in 2005 and expect to incur substantial costs for these lots in the future. 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 and the sales cycle accurately. In addition, we base our internal projections of our blood screening product sales and international sales of diagnostic products on projections prepared by our distributors of these products and therefore we are dependent upon the accuracy of those projections. 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. In addition, the trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about our business and that of our competitors.

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

We rely on Novartis to distribute our blood screening products and Bayer to distribute some of our viral clinical diagnostic products. Commercial product sales by Novartis accounted for 44% of our total revenues for the first quarter of 2006 and 42% of our total revenues for 2005. Our agreement with Novartis will terminate in 2012 unless extended by the development of new products under the agreement, in which case the agreement will expire upon the later of the end of the original term or five years after the first commercial sale of the last new product developed during the original term.

Table of Contents

On April 19, 2006, Chiron stockholders approved a merger agreement whereby Novartis AG would acquire 100% ownership of Chiron and Chiron would become, by merger, a wholly owned, indirect subsidiary of Novartis. Following stockholder approval, the transaction closed on April 20, 2006. In connection with the merger, Chiron Corporation changed its name to Novartis Vaccines and Diagnostics, Inc. Novartis has indicated its intention to continue to operate its blood testing business unit under the trade name Chiron. Prior to the merger, Novartis owned approximately 43.6% of Chiron s shares. We do not know what effect, if any, the merger will have on our blood screening collaboration.

In February 2001, we commenced an arbitration proceeding against Chiron in connection with our blood screening collaboration. The arbitration was resolved by mutual agreement in December 2001. In the event that we or Novartis commence arbitration against each other in the future under the collaboration agreement, proceedings could delay or decrease our receipt of revenue from Novartis or otherwise disrupt our collaboration with Novartis, which could cause our revenues to decrease and our stock price to decline.

Our agreement with Bayer for the distribution of our products will terminate in 2010. In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by us for the detection of HIV, hepatitis virus and other specified viruses, subject to specific conditions. Our demand for arbitration stated that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. In June 2005, the arbitrator issued an Interim Opinion and Award and determined, among other things, that we are entitled to a co-exclusive right to distribute qualitative TMA assays to detect HCV and HIV-1 for the remaining term of the agreement. Bayer previously held the exclusive rights to market these products. We will be required to pay running sales royalties to Bayer on sales of the TMA assays for HCV and HIV-1, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents. The arbitrator also determined that the collaboration agreement should be prospectively terminated, as we requested. As a result of a termination of the agreement, we will have the right to develop and market future viral assays that had been previously reserved for Bayer. Bayer will retain co-exclusive rights to distribute two products that it currently markets. The arbitrator s final decision in this matter is subject to a right to appeal to an arbitration appeal panel within JAMS. There can be no assurances as to the final outcome of the arbitration. We are also involved in patent litigation with Bayer.

We rely upon bioMérieux for distribution of certain of our products in most of Europe, Rebio Gen, Inc. for distribution of certain of our products in Japan, and various independent distributors for distribution of our products in other regions. Distribution rights revert back to us upon termination of the distribution agreements. Our distribution agreement with Rebio Gen terminates on December 31, 2010, although it may terminate earlier under certain circumstances. Our distribution agreement with bioMérieux terminates on May 2, 2009, although it may terminate earlier under certain circumstances.

If any of our distribution or marketing agreements is terminated, particularly our agreement with Novartis, and we are unable to renew or enter into an alternative agreement, or if we elect to distribute new products directly, we will have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to market successfully our products, our product sales will 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 Novartis 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. In addition, we expect to rely on our corporate collaborators for the commercialization of some of our products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its 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.

The continuation of any of our collaboration agreements depends on their periodic renewal by us and our collaborators. For example, our agreement with Novartis will terminate in 2012 unless extended by the development of new products under the agreement, in which case it will expire upon the later of the original term or five years after the first commercial sale of the last new product developed during the original term. We do not know what effect, if any, the merger will have on our relationship with Novartis. Subject to the final outcome of our arbitration with Bayer, the remaining provisions of our Bayer collaboration agreement

will terminate in 2010. Both collaboration agreements are also subject to termination prior to expiration upon a material breach by either party to the agreement.

If any of our collaboration agreements is terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to devote additional internal resources to product development or marketing or to terminate some development programs or seek alternative corporate collaborations. We may not be able to negotiate additional corporate collaborations on acceptable terms, if at all, and these collaborations may not be successful. In addition, in the event of a dispute under our current or any future collaboration agreements, such as those under our agreements with Novartis and Bayer, a court or arbitrator may not rule in our favor and our rights or obligations under an agreement subject to a dispute may be adversely affected, which may have an adverse impact on our business or operating results.

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

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

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, 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 seeking and 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, in October 2005, the FDA notified us that it considers our TIGRIS instrument to be used for screening donated human blood with the Procleix Ultrio assay not substantially equivalent to our already cleared eSAS. The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. Also in October 2005, we received a complete review letter from the FDA setting forth questions regarding our BLA for the Procleix Ultrio assay itself. There can be no assurance that the Procleix Ultrio assay will receive regulatory approval by the FDA or that the TIGRIS instrument will receive FDA clearance for use with the WNV or Procleix Ultrio assays.

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 regulatory requirements once we have obtained clearance or approval for a product. These requirements include, among other things, the Quality System Regulation, labeling requirements, the FDA s general prohibition against promoting products for unapproved or off-label uses and adverse event reporting regulations. Failure to comply with applicable FDA product regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications and criminal prosecution. Any of these actions, in combination or alone, could prevent us from selling our products and harm our business.

Outside the United States, our ability to market our products is contingent upon maintaining our International Standards Organization (ISO) certification, and in some cases receiving specific marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. Our EU foreign marketing authorizations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

Table of Contents

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. 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 that 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.

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 Roche Molecular Systems, or Roche, Abbott Laboratories, Becton Dickinson and bioMérieux, 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. Many of our competitors have, and in the future these and other competitors may have, significantly greater financial, marketing, sales, manufacturing, distribution and technological resources than us. Moreover, these companies may have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do. In addition, we have licensed some of our proprietary technology relating to certain clinical diagnostic and food pathogen applications for use on specific instruments to bioMérieux, and we may license other technologies to potential competitors in the future. As a result, we may in the future compete with bioMérieux and these other licensees for sales of products incorporating our technology. Our competitors may be in better position to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners than we are. Some of our competitors have developed real time or kinetic nucleic acid assays and semi-automated instrument systems for those assays. Our competitors may be further in the development process than we are with respect to such assays and instrumentation.

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

Novartis, with whom we have a collaboration agreement for our blood screening products, retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening. Prior to its merger with Novartis, Chiron granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron also granted HIV and HCV licenses in the clinical diagnostics 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 also granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux) in the clinical diagnostics field. To the extent that Novartis 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 gross profit margin percentage on the sale of blood screening assays may decrease upon the implementation of individual donor testing.

We currently receive revenues from the sale of our blood screening assays primarily for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test. However, Novartis sells our blood screening assays to blood

collection centers on a per donation basis. We expect the blood screening market ultimately to transition from pooled testing to individual donor testing. A greater number of tests will be required for individual donor testing than are now required for pooled testing. Under our collaboration agreement with Novartis, we bear the cost of manufacturing our blood screening assays. 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 margin percentage from sales of the blood screening assay may decrease upon the adoption of individual donor testing. We are not able to predict accurately the extent to which our gross profit margin percentage may be negatively affected as a result of individual donor testing, because we do not know the ultimate selling price that Novartis 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 Novartis. Our blood screening collaboration with Novartis accounted for 52% of our total revenues for the first quarter of 2006 and 52% of our total revenues for 2005. Our blood screening collaboration with Novartis 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. Novartis was our only customer that accounted for greater than 10% of our total revenues for the three months ended March 31, 2006. 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 first quarter of 2006 and 20% of our total revenues for 2005. Although state and city public health agencies are legally independent of each other, we believe 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.

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 had more than 400 United States and foreign patents covering our products and technologies as of March 31, 2006, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by August 29, 2023, 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. Bayer recently initiated litigation against us alleging that we are developing real-time diagnostic assays for HIV and HCV without the authorization of the patent owner.

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

Table of Contents

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 have been and may continue to 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. From time-to-time in the ordinary course of business we receive communications from third parties calling our attention to patents or other intellectual property rights owned by them, with the implicit or explicit suggestion that we may need to acquire a license of such rights. We have faced in the past, are currently facing, and may face in the future, patent infringement lawsuits by companies that control patents for products and services similar to ours or other lawsuits alleging infringement by us of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management s attention from other business concerns. The cost of this litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

Recently, we have been involved in a number of patent disputes with third parties, including Bayer, some of which remain unresolved. Additionally, we hold certain rights in the blood screening and clinical diagnostics fields under patents issued to Chiron covering the detection of HIV. In February 2005, the U.S. Patent and Trademark Office declared two interferences related to U.S. Patent No. 6,531,276 (Methods For Detecting Human Immunodeficiency Virus Nucleic Acid) (the 276 patent), issued to Chiron (now Novartis). The first interference is between Novartis and Centocor, Inc., and pertains to Centocor s U.S. Patent Application No. 06/693,866 (Cloning and Expression of HTLV-III DNA) (the 866 application). The second interference is between Novartis and Institut Pasteur, and pertains to Institut Pasteur s U.S. Patent Application No. 07/999,410 (Cloned DNA Sequences, Hybridizable with Genomic RNA of Lymphadenopathy-Associated Virus (LAV)) (the 410 application). Novartis is the junior party in both interferences. In February 2005, at about the time the interferences were declared, we received a letter from the Institut Pasteur regarding alleged infringement of Institut Pasteur s European Patent EP 0 178 978 (Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus, or LAV) (978 patent), by the HIV-1 nucleic acid screening assays performed on our Procleix system that is marketed and distributed by Novartis. There can be no assurances as to the ultimate outcomes of these matters.

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

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

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

As of March 31, 2006, we had approximately $208.1 million of long-lived assets, including $20.3 million of capitalized software relating to our TIGRIS instrument, goodwill of $18.6 million, a $2.5 million investment in Molecular Profiling Institute, Inc., and $48.1 million of capitalized license and manufacturing fees, patents and purchased intangibles. Additionally, we had $31.6 million of land and building, $3.8 million of leasehold improvements, $44.1 million of construction in-progress and $39.1 million of equipment

and furniture and fixtures. The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. These events or changes might include a significant decline in market share, a significant decline in profits, rapid changes in technology, significant litigation or other matters. Adverse events or changes in circumstances may affect the estimated undiscounted future operating cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise 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 markets for our products are characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products, including with our industrial collaborators. We believe that we will need to continue to provide new products that can detect a greater number of organisms from a single sample. We also believe that we must develop new assays that can be performed on automated instrument platforms, such as our TIGRIS instrument.

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends, as well as precise technological execution. In addition, the successful development of new products will depend on the development of new technologies. We may be required to undertake time-consuming and costly development activities and to seek regulatory approval for these new products. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of these new products. For example, we recently announced delays in FDA clearance for our TIGRIS instrument for blood screening with the Procleix Ultrio assay and for our BLA for the Procleix Ultrio assay itself. Regulatory clearance or approval of these and any other new products may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and these and other new products may not be successfully commercialized.

We recently entered into collaboration agreements to develop NAT products for industrial testing applications. We have limited experience operating in these markets and may not successfully develop commercially viable products.

In July and August 2005 we entered into collaboration agreements to develop NAT products for detecting microorganisms in selected water applications and for microbiological and virus monitoring in the biotechnology and pharmaceutical manufacturing industries. Our experience to date has been primarily focused on developing products for the clinical diagnostic and blood screening markets. We have limited experience applying our technologies and operating in these new industrial testing markets. The process of successfully developing products for application in these potential markets is expensive, time-consuming and unpredictable. Research and development programs to create new products require a substantial amount of our scientific, technical, financial and human resources even if no new products are successfully developed. We will need to make significant investments to ensure that any products we develop perform properly, are cost-effective and adequately address customer needs. Even if we develop products for commercial use in these markets, any products we develop may not be accepted in these markets, may be subject to competition and may be subject to other risks and uncertainties associated with these new markets. We have no experience with customer and customer support requirements, sales cycles, and other industry-specific requirements or dynamics applicable to these new markets and we and our collaborators may not be able to successfully convert customers from traditional culture and other testing methods to tests using our NAT technologies, which we expect will be more expensive than existing methods. We will be reliant on our collaborators and their experience and expertise in addressing customer needs and other requirements in these markets. Our interests may be different from those of our collaborators and conflicts may arise in these collaboration arrangements that have an adverse impact on our ability to develop new products. As a result of these risks and other uncertainties, there is no guarantee that we will be able to successfully develop commercially viable products for application in industrial testing or any other new markets.

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 and clinical diagnostic products and our TIGRIS instrument. We expect our expense levels to remain high in connection with our research and development as we continue to expand our product offerings and continue to develop products and technologies in collaboration with our strategic partners. As a result, we will need to continue to generate significant revenues to maintain profitability. Although we expect our research and development expenses as a percentage of revenue to decrease in future periods, we may not be able to

generate revenues and may not maintain profitability in the future. Our failure to maintain profitability in the future could 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, we may in the future need to incur debt or issue equity in order to fund these requirements, as well as to make acquisitions and other investments. If we cannot obtain debt or equity financing on acceptable terms or are limited with respect to incurring 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, for example, for research and development to successfully develop new technologies and products, and to acquire new technologies, products or companies.

If we raise funds through the issuance of debt or equity, 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 any 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 result in dilution to our stockholders.

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 control, quality assurance and costs.

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is the only manufacturer of our TIGRIS instrument. MGM Instruments, Inc. is the only manufacturer of our LEADER series of luminometers. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have no firm long-term commitments from KMC Systems, MGM Instruments or any of our other manufacturers to supply products to us for any specific period, or 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, we believe qualifying a new manufacturer of our TIGRIS instrument would take approximately 12 months. If we are required or elect to change contract manufacturers, we may lose revenues and our customer relationships may suffer.

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

We must manufacture or have manufactured our products in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs and complying with regulatory requirements. In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products we and our distributors require, which could harm our business and results of

operations.

Table of Contents

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. For example, we anticipate that we will need to develop closed unit dose assay pouches containing both liquid and dried reagents to be used in industrial applications, which will be a new process for us. We may be unable to develop the required technologies or expertise.

The amplified NAT tests that we produce 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 and our margins may decline. 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 margin percentages. 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 and validation 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 and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States and the European Union, certain tests may also require individual lot release testing. Maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our overall manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies, and these facilities are subject to Quality System Regulations requirements of the FDA. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

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

The FDA and governmental bodies in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to product manufacturing, quality, labeling, advertising, or promotional activities, or if new information is obtained concerning the safety of a product. A government-mandated recall, or a voluntary recall by us, could divert managerial and financial resources and potentially harm our reputation with customers. In the past, we have had four voluntary recalls, which, in each case, required us to identify and correct the problem. For example, we experienced a recall in June 2004 as a result of a customer complaint about our Mycobacterium Tuberculosis product suggesting reduced stability of one of our reagents. The problem was identified and corrected and customers were provided with replacement reagent. Our products may be subject to additional recalls in the future. Future recalls could be more difficult and costly to correct, may result in the suspension of sales of our products, and may harm our financial results and our reputation.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 25% of our total revenues for the first quarter of 2006 and 21% of our total revenues for 2005. Sales by Novartis of our blood screening products outside of the United States accounted for 85% of our international revenues for the first quarter of 2006 and 78% of our international revenues for 2005. Novartis has responsibility for the international distribution of our blood screening products, which includes sales in France, Australia, Singapore, New Zealand, South Africa, Italy and other countries. Our sales in France and Japan that were not made through Novartis accounted for 5% and 4%, respectively, of our international sales for the first quarter of 2006 and 5% of our international sales for 2005.

We encounter risks inherent in international operations. We expect a significant portion of our sales growth, especially with respect to our blood screening products, to come from expansion in international markets. 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,

Table of Contents

- 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.

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

In addition, we anticipate that requirements for smaller pool sizes or ultimately individual donor testing of blood samples, if and when implemented, could result in lower gross margin rates, as additional tests would be required to deliver the sample results, unless a corresponding increase in sales price is implemented. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion may lead to lower gross margin rates.

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

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

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

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

Disruptions in the supply of raw materials and consumable goods from our single source suppliers, including Roche Molecular Biochemicals, 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 and consumable goods 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 certain key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is Roche Molecular Biochemicals, and we have a supply agreement for nucleic acids for human papillomavirus with Roche Molecular Systems, each of which are affiliates of Roche Diagnostics GmbH, one of our primary competitors. 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 also have single source suppliers for proposed future products. Failure to maintain existing supply relationships or to obtain suppliers for our future products, if any, on commercially reasonable terms would prevent us from manufacturing our future products and limit our growth.

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

We are dependent on licenses from third parties for some of our key technologies. For example, our patented Transcription-Mediated Amplification technology is based on technology we have licensed from Stanford University and the chemiluminescence technology we use in our products is based on technology licensed by our consolidated subsidiary, Molecular Light Technology Limited, from the University of Wales College of Medicine. We enter into new licensing arrangements in the ordinary course of business to expand our product portfolio and access new technologies to enhance our products and develop new products. 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. Third parties that license technologies to us also may be acquired by our competitors or may otherwise attempt to terminate or restrict our licenses for their commercial benefit. In addition, 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. Our ability to design products that target these diseases may depend 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 access new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

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

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

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, or 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 acquire other businesses or form collaborations, strategic alliances and joint ventures that could decrease our profitability, result in dilution to stockholders or cause us to incur debt or significant expense.

As part of our business strategy, we intend to pursue acquisitions of complementary businesses and enter into 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 forming collaborations, strategic alliances and joint ventures. 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 result in dilution to our stockholders. If the price of our equity is low or volatile, we may not be able to use our common stock as consideration 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.

Table of Contents

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 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. Our facilities may be harmed by natural or man-made disasters, including, without limitation, earthquakes and fires, and in the event they are affected by a disaster, we would be forced to rely on third-party manufacturers. In the event of a disaster, we may lose customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

Our research and development activities and our manufacturing activities involve the controlled use of infectious diseases, potentially harmful biological materials, as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury, and we could be held liable for damages that result from any 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 our stockholders may favor.

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 our stockholders may favor. Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15 percent of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or its affiliate crosses the 15 percent stock ownership threshold.

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

We may not successfully integrate acquired businesses or technologies.

Through a series of transactions concluding in May 2005, we acquired all of the outstanding shares of Molecular Light Technology Limited and its subsidiaries and, in the future, we may acquire additional businesses or technologies. Managing this acquisition and any future acquisitions will entail numerous operational and financial risks, including:

the inability to retain or replace 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 could 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 could be difficult and costly; and
- integrating or completing the development and application of any acquired technologies, which could 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, 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 revenue or expense fluctuations and affect our reported results of operations.

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

Information technology systems implementation issues could disrupt our internal operations and adversely affect our financial results.

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

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

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

Table of Contents

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 have invested and intend to invest all reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

Item 5. Other Information

On May 1, 2006, the Company entered into an amendment to its distributorship agreements with bioMerieux pursuant to which the parties agreed to extend the term of bioMerieux s exclusive distribution rights for certain products in specified countries until May 2, 2009.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description
2.1(1)	Separation and Distribution Agreement, dated and effective as of May 24, 2002, and amended and restated as of August 6, 2002, by and between Chugai Pharmaceutical Co., Ltd. and Gen-Probe Incorporated.
3.1(1)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(5)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(1)	Form of Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(5)	Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)	Specimen common stock certificate.
4.2(2)	Rights Agreement, dated as of September 16, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C.
4.3(3)	First Amendment to Rights Agreement, dated October 9, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC.
4.4(4)	Second Amendment to Rights Agreement, dated November 20, 2003.
10.88	Amendment No. 8 effective February 8, 2006 to the Agreement dated as of June 11, 1998 between Gen-Probe Incorporated and Chiron Corporation.
10.89	2006 Amendment to the Renewed Distributorship Agreement and the Distributorship Arrangements Agreement dated May 2, 1997 by and between Gen-Probe Incorporated and bioMerieux S.A. entered into May 1, 2006.
31.1	Certification dated May 5, 2006, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification dated May 5, 2006, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1

Certification dated May 5, 2006, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2

Certification dated May 5, 2006, 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.

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: May 5, 2006	By:	/s/ Henry L. Nordhoff Henry L. Nordhoff Chairman, President and Chief Executive Officer (Principal Executive Officer)
DATE: May 5, 2006	By:	/s/ Herm Rosenman Herm Rosenman Vice President Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)