GEN PROBE INC
Form 10-Q
November 01, 2006

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

þ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 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	**33-0044608**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
10210 Genetic Center Drive San Diego, CA	**92121**
(Address of Principal Executive Offices)	(Zip Code)

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

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

Indicate by check mark whether the registrant is 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 October 31, 2006, there were 52,065,600 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

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

	September 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,066	$ 32,328
Short-term investments	209,454	187,960
Trade accounts receivable, net of allowance for doubtful accounts of $670 and $790 at September 30, 2006 and December 31, 2005, respectively	24,303	31,930
Accounts receivable other	2,171	1,924
Inventories	44,524	36,342
Deferred income taxes	10,030	10,389
Prepaid expenses	11,450	10,768
Other current assets	4,977	4,184
Total current assets	368,975	315,825
Property, plant and equipment, net	130,289	105,190
Capitalized software	19,066	20,952
Goodwill	18,621	18,621
License, manufacturing access fees and other assets	56,074	49,648
Total assets	$ 593,025	$ 510,236
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 10,948	$ 14,029
Accrued salaries and employee benefits	18,324	14,910
Other accrued expenses	3,955	3,264
Income tax payable	7,582	13,192
Deferred revenue	4,296	7,771
Total current liabilities	45,105	53,166
Deferred income taxes	5,425	5,124
Deferred revenue	3,833	4,333
Deferred rent	153	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, 52,051,761 and 51,137,541 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	5	5
Additional paid-in capital	322,302	281,907
Deferred compensation		(5,951)

Accumulated other comprehensive income (loss)	281	(1,231)
Retained earnings	215,921	172,643
Total stockholders equity	538,509	447,373
Total liabilities and stockholders equity	$ 593,025	$ 510,236

See accompanying notes to consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Product sales	$ 83,470	$ 68,941	$ 239,811	$ 193,651
Collaborative research revenue	1,470	6,336	14,743	19,358
Royalty and license revenue	7,287	994	9,151	4,984
Total revenues	92,227	76,271	263,705	217,993
Operating expenses:				
Cost of product sales	23,801	21,399	74,715	57,247
Research and development	24,178	17,506	63,833	53,597
Marketing and sales	9,526	7,555	27,533	22,365
General and administrative	12,748	7,822	34,104	22,793
Total operating expenses	70,253	54,282	200,185	156,002
Income from operations	21,974	21,989	63,520	61,991
Total other income, net	1,921	1,318	5,081	3,400
Income before income taxes	23,895	23,307	68,601	65,391
Income tax expense	8,779	6,890	25,323	22,057
Net income	$ 15,116	$ 16,417	$ 43,278	$ 43,334
Net income per share:				
Basic	$ 0.29	$ 0.32	$ 0.84	$ 0.86
Diluted	$ 0.28	$ 0.31	$ 0.82	$ 0.83
Weighted average shares outstanding:				
Basic	51,638	50,726	51,407	50,518
Diluted	53,180	52,464	53,001	52,381

Net income for the three and nine month periods ended September 30, 2006 included stock-based compensation expense that the Company recorded as a result of the adoption of Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, on January 1, 2006. For the three months ended September 30, 2006, this expense totaled $6,379,000 before income taxes (after deducting $287,000 of net capitalization to inventory on the Company s balance sheet) and $4,048,000 net of income taxes for the period. For the nine months ended September 30, 2006, stock-based compensation expense totaled $16,154,000 before income taxes (after deducting $1,159,000 that has been capitalized to inventory on the Company s balance sheet) and $10,372,000 net of income taxes for the period. The Company did not record stock-based compensation expense for the three and nine month periods ended September 30, 2005. As previously disclosed in the notes to the financial statements for the three and

nine month periods ended September 30, 2005, net income including pro forma stock-based compensation expense was $12,578,000 and $31,863,000, respectively. See Note 3 to the financial statements for additional information.

See accompanying notes to consolidated financial statements.

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

	Nine Months Ended September 30,	
	2006	**2005**
Operating activities		
Net income	$ 43,278	$ 43,334
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	19,752	16,694
Stock-based compensation charges restricted stock	1,601	445
Stock-based compensation charges all other	16,154	
Stock option income tax benefits	111	6,948
Excess tax benefit from employee stock options	(8,232)	
Loss on disposal of property and equipment	4	262
Changes in assets and liabilities:		
Accounts receivable	7,550	(5,562)
Inventories	(6,830)	(6,809)
Prepaid expenses	(682)	(3,760)
Other assets	(798)	(2,033)
Accounts payable	(3,103)	5,525
Accrued salaries and employee benefits	3,414	4,767
Other accrued expenses	624	(1,169)
Income tax payable	2,615	6,467
Deferred revenue	(3,975)	5,253
Deferred income taxes	645	(2,134)
Deferred rent	(87)	(47)
Net cash provided by operating activities	72,041	68,181
Investing activities		
Proceeds from sales and maturities of short-term investments	83,641	98,693
Purchases of short-term investments	(104,163)	(105,672)
Cash paid for acquisition of minority interest in Molecular Light Technology Limited		(1,539)
Purchases of property, plant and equipment	(40,126)	(29,894)
Capitalization of intangible assets, including license and manufacturing access fees	(2,245)	(22,450)
Cash paid for investment in Qualigen, Inc.	(6,993)	
Other assets	(223)	(821)
Net cash used in investing activities	(70,109)	(61,683)
Financing activities		
Excess tax benefit from employee stock options	8,232	
Proceeds from issuance of common stock	19,089	13,963
Net cash provided by financing activities	27,321	13,963

Effect of exchange rate changes on cash and cash equivalents	485	(369)
Net increase in cash and cash equivalents	29,738	20,092
Cash and cash equivalents at the beginning of period	32,328	25,498
Cash and cash equivalents at the end of period	$ 62,066	$ 45,590

See accompanying notes to consolidated financial statements.

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Notes to the Consolidated Financial Statements (unaudited)

Note 1 Basis of presentation

The accompanying interim consolidated financial statements of Gen-Probe Incorporated (Gen-Probe or the Company) at September 30, 2006, and for the three and nine month periods ended September 30, 2006 and 2005, are unaudited and have been prepared in accordance with United States generally accepted accounting principles (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 and nine month periods ended September 30, 2006 includes approximately $6,379,000 and $16,154,000 respectively, 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 expense.

Note 2 Summary of significant accounting policies

Recent accounting pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 (FIN 48) Accounting for Uncertainty in Income Taxes an interpretation of SFAS No. 109 which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently assessing the impact of FIN 48 on its consolidated financial position and results of operations.

In December 2004, the FASB issued revised Statement No. 123(R) Share-Based Payment (SFAS No. 123(R)), 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.

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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 the minority 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 access and license fees, income taxes, and liabilities associated with employee benefit costs. 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, 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 income (loss).

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-Merton 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 unrecognized compensation expense, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested stock-based awards was approximately as follows (in thousands):

Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of September 30, 2006
Options	1.8	$ 40,424
ESPP	0.2	71
Restricted stock	1.8	8,948
Deferred issuance restricted stock	1.5	2,013
		$ 51,456

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 $16,154,000 in stock-based compensation recognized in the first nine months of 2006 related to the adoption of SFAS No. 123(R), approximately $13,654,000 was related to awards granted prior to January 1, 2006 and $2,500,000 was related to awards granted during the first nine months of 2006. Additionally, in each of May 2006 and 2005, the Company granted to its chief executive officer 20,000 shares of Deferred Issuance Restricted Stock Awards at the fair market value of these awards on the date of grants. The total fair values of approximately $1,054,000 and $871,000, respectively, are being amortized to expense on a straight-line basis over the vesting periods (48 months).

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At September 30, 2006, the Company had 269,586 unvested restricted stock and deferred issuance restricted stock awards that had a weighted average grant date fair value of $46.00 per share. The fair value of the 15,417 restricted stock and deferred issuance restricted stock awards that vested during the first nine months of 2006 was approximately $597,000.

Expected term

The expected term of stock options granted represents the period of time that they are expected to be outstanding. Historically, the Company determined the expected term of options based on Section 16 insider reported data from a select group of peer companies. In May 2006, the Company s stockholders approved an amendment and restatement of The 2003 Incentive Award Plan (the 2003 Plan) that decreased the maximum contractual term of the Company s prospective option grants from ten years to seven years. Corresponding with this change, the Company revised its determination of the expected term of options by applying a weighted-average calculation combining the average life of Company options that have already been exercised with the estimated life of all unexercised options.

Expected volatility

Historically, the Company determined the expected volatility of its stock options granted by relying exclusively on the Company s historical stock price changes (using daily pricing). During 2005, the Company determined that a more appropriate estimate is obtained by taking an average of the Company s historical stock price changes (using daily pricing) and the implied volatility on its traded options, consistent with SFAS No. 123(R) and SAB No. 107.

Risk-free interest rate

The Company determines the risk-free interest rate that it uses in the Black-Scholes-Merton 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-Merton 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 and nine month periods ended September 30, 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.

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Assumptions

The Company used the following assumptions to estimate the fair value of options granted and the shares purchased under the Company s Employee Stock Purchase Plan (ESPP) for the three and nine month periods ended September 30, 2006 and 2005.

	Stock Option Plans				ESPP			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005	2006	2005	2006	2005
Risk-free interest rate	4.8%	3.9%	4.8%	3.8%	5.0%	3.4%	4.4%	3.0%
Volatility	42%	45%	42%	53%	38%	40%	40%	48%
Dividend yield								
Expected term (years)	4.2	5.4	4.5	4.9	0.5	0.5	0.5	0.5
Resulting average fair value	$ 19.87	$ 19.76	$ 20.93	$ 22.18	$ 13.48	$ 9.14	$ 12.99	$ 10.86

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 option grants 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 September 30, 2005	Nine Months Ended September 30, 2005
Net income:		
As reported	$ 16,417	$ 43,334
Stock-based employee compensation expense included in reported net income, net of related tax effects	87	206
Total stock-based employee compensation expense determined under fair value based method for all options, net of related tax effects	(3,926)	(11,677)
Pro forma net income	$ 12,578	$ 31,863
Net income per share:		
As reported		
Basic	$ 0.32	$ 0.86
Diluted	$ 0.31	$ 0.83
Pro forma		
Basic	$ 0.25	$ 0.63

Diluted	$	0.24	$	0.61

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

The following table summarizes the stock-based compensation expense for stock option grants and ESPP shares that the Company recorded in its statements of income in accordance with SFAS No. 123(R) for the three and nine month periods ended September 30, 2006 (in thousands, except per share data):

		Three Months Ended September 30, 2006		**Nine Months Ended September 30, 2006**
Cost of product sales	$	743	$	1,366
Research and development		2,024		5,698
Marketing and sales		863		2,335
General and administrative		2,749		6,755
Reduction of operating income before income taxes		6,379		16,154
Income tax benefit		(2,331)		(5,782)
Reduction of net income	$	4,048	$	10,372
Reduction of net income per share:				
Basic	$	0.08	$	0.20
Diluted	$	0.08	$	0.19

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The carrying value of inventory on the Company s balance sheet as of September 30, 2006 includes capitalized employee stock-based compensation costs of $1,159,000.

Prior to the adoption of SFAS No. 123(R), the Company presented deferred compensation related to shares of deferred issuance restricted stock and 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.

Note 4 Short-term investments

The following is a summary of short-term investments as of September 30, 2006 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal securities	$ 204,917	$ 330	$ (1,058)	$ 204,189
Foreign debt securities	5,265			5,265
Total short-term investments	$ 210,182	$ 330	$ (1,058)	$ 209,454

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 September 30, 2006 (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Municipal securities	$ 36,903	$ (201)	$ 89,304	$ (857)
Foreign debt securities				
Total short-term investments	$ 36,903	$ (201)	$ 89,304	$ (857)

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 data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005

Net income	$ 15,116	$ 16,417	$ 43,278	$ 43,334
Weighted average shares outstanding Basic	51,638	50,726	51,407	50,518
Effect of dilutive common stock options outstanding	1,542	1,738	1,594	1,863
Weighted average shares outstanding Diluted	53,180	52,464	53,001	52,381
Net income per share:				
Basic	$ 0.29	$ 0.32	$ 0.84	$ 0.86
Diluted	$ 0.28	$ 0.31	$ 0.82	$ 0.83

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Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 1,437,857 and 208,735 for the three month periods ended September 30, 2006 and 2005, respectively, and 1,149,091 and 187,957 shares for the nine month periods ended September 30, 2006 and 2005, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

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 the Company s subsidiaries, and unrealized gains and losses on its available for sale securities.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net income	$ 15,116	$ 16,417	$ 43,278	$ 43,334
Foreign currency translation adjustment	(68)	(244)	1,050	(562)
Change in unrealized gain (loss) on investments	1,023	(238)	462	(726)
Comprehensive income	$ 16,071	$ 15,935	$ 44,790	$ 42,046

Note 7 Balance sheet information

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

Inventories

	September 30, 2006	December 31, 2005
Raw materials and supplies	$ 6,160	$ 5,430
Work in process	21,348	17,934
Finished goods	17,016	12,978
	$ 44,524	$ 36,342

Property, plant and equipment

	September 30, 2006	December 31, 2005
Land	$ 13,862	$ 9,100
Buildings	71,316	39,535
Machinery and equipment	122,777	106,433
Tenant improvements	26,570	16,301
Furniture and fixtures	15,471	10,346
Construction in-progress	990	32,143
Property, plant and equipment (at cost)	250,986	213,858

Less accumulated depreciation and amortization	(120,697)	(108,668)
Property, plant and equipment (net)	$ 130,289	$ 105,190

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License, manufacturing access fees and other assets

	September 30, 2006			December 31, 2005		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Intangible assets subject to amortization:						
Capitalized software	$ 25,142	$ 6,076	$ 19,066	$ 25,142	$ 4,190	$ 20,952
Patents	16,468	15,186	1,282	15,822	14,817	1,005
Purchased intangible assets	33,636	32,582	1,054	33,636	32,330	1,306
License and manufacturing access fees	49,958	5,713	44,245	48,354	3,517	44,837
Total	$ 125,204	$ 59,557	$ 65,647	$ 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
Investment in Qualigen, Inc.	$ 6,993	$	$ 6,993	$	$	$

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.

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) system based on Qualigen s Food and Drug Administration (FDA) approved FastPack® immunoassay system. If development is successful, the new system, known as a closed unit-dose assay (CUDA) system, would use the Company s NAT technologies to detect microorganisms and genetic mutations at the point of sample collection. As a result 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-1 Convertible Preferred Non-Voting Stock convertible into approximately 19.5% of Qualigen s capital stock, on an as converted to common stock basis, as of the purchase date. Gen-Probe may also pay Qualigen up to $3,000,000 based on achievement of development milestones under the license agreement and agreed to pay Qualigen royalties on sales of any product developed by Gen-Probe under the agreement. The Company has recorded this investment as an intangible asset on a cost basis, and will review the asset for impairment on an ongoing basis.

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 believes, more likely than not, that it

will have sufficient taxable income after stock option related deductions to utilize the majority of its deferred tax assets.

Tax benefits of $8,343,000 and $6,948,000 in the nine month periods ended September 30, 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. The 2003 Plan provides for equity 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 stock option granted under the 2003 Plan must be equal to or greater than the fair market value of the Company s common stock on the date of grant. Generally, stock options granted under the 2003 Plan are subject to vesting 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.

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In May 2006, the Company s stockholders approved an amendment and restatement of the 2003 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2003 Plan by 3,000,000 shares, from 5,000,000 shares to 8,000,000 shares. Pursuant to the amended 2003 Plan, the Board of Directors or Compensation Committee may continue to determine the terms and vesting of all options and other awards granted under the 2003 Plan; however, in no event may the award term exceed seven years (in lieu of ten years under the 2003 Plan prior to its amendment). Further, the number of shares available for issuance under the amended 2003 Plan are reduced by two shares for each one share of restricted stock granted under the 2003 Plan after May 17, 2006 (in lieu of a reduction of one share under the 2003 Plan prior to its amendment).

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 authorized 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 to employees, directors and consultants of the Company. 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	1,421,008	50.20		
Exercised	(760,239)	22.85		
Cancelled	(181,451)	39.69		
Outstanding at September 30, 2006	6,432,904	$ 34.60	7.18	$ 79,072
Exercisable at September 30, 2006	3,069,699	$ 24.91	6.40	$ 67,463

The Company defines in-the-money options at September 30, 2006 as options that had exercise prices that were lower than the $46.89 market price of its common stock at that date. The aggregate intrinsic value of options outstanding at September 30, 2006 is calculated as the difference between the exercise price of the underlying options and the market price of its common stock for the 4,827,220 shares that were in-the-money at that date. The total intrinsic value of options exercised during the first nine months of 2006 was $22,403,000, determined as of the exercise dates. The total fair value (using Black-Scholes-Merton Model) of shares vested during the first nine months of 2006 was $13,331,000.

A summary of the Company s unvested stock options at September 30, 2006 and changes during the first nine months then ended is as follows:

		Weighted

	Number of Shares	Weighted Average Grant-Date Fair Value	Average Remaining Contractual Life (Years)
Non-vested at December 31, 2005	3,013,536	$ 17.09	
Granted	1,421,008	20.93	
Vested	(890,983)	14.33	
Forfeited	(180,356)	18.45	
Non-vested at September 30, 2006	3,363,205	$ 19.48	7.89

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During the three and nine months ended September 30, 2006, options to purchase 150,888 and 760,239 shares of the Company s common stock were exercised by Gen-Probe employees at a weighted average exercise price of $28.25 and $22.85, respectively. The Company also issued 629 and 1,998 shares of restricted common stock at fair market value during the three and nine month periods ended September 30, 2006, respectively, to members of the Board of Directors as partial consideration for services rendered. The Company recognized expense for these shares issued to the members of the Board of Directors during the three and nine month periods ended September 30, 2006, of $34,000 and $105,000, respectively, which was equal to the fair market value on the dates of issuance. Employees purchased 41,480 shares of the Company s common stock at $41.47 per share during the nine months ended September 30, 2006 pursuant to the Company s ESPP.

Changes in stockholders equity for the nine months ended September 30, 2006 were as follows (in thousands):

Balance at December 31, 2005	$ 447,373
Net income	43,278
Other comprehensive income, net	1,512
Net proceeds from the issuance of common stock	17,369
Purchase of common shares through ESPP	1,720
Purchase of common stock by board members	105
Stock-based compensation expense restricted stock	1,496
Stock-based compensation expense all other	16,154
Stock-based compensation net capitalized to inventory	1,159
Tax benefit from the exercise of stock options	8,343
Balance at September 30, 2006	$ 538,509

Note 10 Litigation

In June 2006, the Company entered into a Short Form Settlement Agreement with Bayer HealthCare LLC and Bayer Corp. (collectively, Bayer), to resolve patent litigation filed by the Company against Bayer in the United States District Court for the Southern District of California and to resolve separate commercial arbitration proceedings between the parties. On August 1, 2006, the parties signed final, definitive settlement documentation, referred to herein as the Settlement Agreement. All litigation and arbitration proceedings between the Company and Bayer were terminated pursuant to the Settlement Agreement.

Pursuant to the terms of the Settlement Agreement, the Company dismissed the patent litigation and granted Bayer immunity from suit for all current Bayer nucleic acid diagnostic products. The Company also agreed not to assert four specified patents against future Bayer products. Also, Bayer granted the Company immunity from suit for the Company s current TIGRIS instrument and agreed not to assert certain specified Bayer patents against the Company s future instruments.

Pursuant to the Settlement Agreement, Bayer paid the Company an initial license fee of $5,000,000 in August 2006. Additionally, Bayer agreed to pay approximately $10,300,000 as a one-time royalty if Bayer sells any product subject to the Company patents covered by the Settlement Agreement on or after January 1, 2007, and Bayer also agreed to pay approximately $16,400,000 as a one-time royalty if Bayer sells any product subject to the Company patents on or after January 1, 2008. Subject to these two royalty payments, Bayer s rights to the related Company patents will be fully paid-up and royalty free.

During the third quarter of 2006, the Company recorded the $5,000,000 initial license fee from Bayer as royalty and license fee revenue, and recorded approximately $2,000,000 of additional G&A expense for a payment to the Company s outside litigation counsel in connection with the settlement.

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In accordance with the Settlement Agreement, Bayer dismissed its October 4, 2005 demand for arbitration and a related lawsuit. The parties also submitted a stipulated final award in the original arbitration proceeding filed by the Company against Bayer in November 2002, adopting the arbitrator s prior interim and supplemental awards, except that Bayer is no longer obligated to reimburse the Company $2,000,000 for legal expenses. The arbitrator s June 5, 2005 Interim 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 human immunodeficiency virus (type 1), (HIV-1) for the remaining term of the collaboration agreement between the parties on the Company s DTS 400, 800, and 1200 instrument systems. The arbitrator also determined that the collaboration agreement should be terminated, as the Company requested, except as to the qualitative HCV assays and as to quantitative Analyte Specific Reagents (ASR) for HCV. Bayer retains the co-exclusive right to distribute the qualitative HCV tests and the exclusive right to distribute the quantitative HCV ASR. As a result of the termination of the agreement, the Company re-acquired the right to develop and market future viral assays that had been previously reserved for Bayer. The arbitrator s March 3, 2006 supplemental award determined that the Company is not obligated to pay Bayer an initial license fee in connection with the sale of the qualitative HIV-1 and HCV assays and that the Company will be required to pay running sales royalties, at rates the Company believes are generally consistent with rates paid by other licensees of the relevant patents.

Pursuant to the Settlement Agreement, Bayer granted the Company an option to extend the term of the license granted in the arbitration for qualitative HIV-1 and HCV assays, so that the license would run through the life of the relevant HIV-1 and HCV patents. The option also permits the Company to elect to extend the license to future instrument systems (but not to the TIGRIS instrument). Exercise of the option will require payment of a $1,000,000 fee to Bayer by the Company.

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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 or anticipates, or other similar words (includ 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 September 30, 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 that 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 sales of clinical diagnostic products for sexually transmitted diseases, or STDs, due to the success of APTIMA Combo 2, which is used to test for chlamydia and gonorrhea.

We are currently developing future nucleic acid probe-based products that we hope to introduce in the clinical diagnostic and blood screening markets, including products for the detection of human papillomavirus and for measuring markers for prostate cancer.

Recent Events

Financial results

Product sales for the third quarter of 2006 were $83.5 million, compared to $69.0 million in the same period of the prior year, an increase of 21%. Total revenues for the third quarter of 2006 were $92.3 million, compared to $76.3 million in the same period of the prior year, an increase of 21%. Net income for the third quarter of 2006 was $15.1 million ($0.28 per diluted share), compared to $16.4 million ($0.31 per diluted share) in the same period of the prior year. Net income in the third quarter of 2006 included $4.0 million ($0.08 per diluted share) in stock-based compensation expense due to the adoption of Statement of Financial Accounting Standards No.123(R), Share Based Payment, or SFAS No. 123(R).

Product sales for the first nine months of 2006 were $239.8 million, compared to $193.6 million in the same period of the prior year, an increase of 24%. Total revenues for the first nine months of 2006 were $263.7 million, compared to $218.0 million in the same period of the prior year, an increase of 21%. Net income for the first nine months of 2006 was $43.3 million ($0.82 per diluted share), compared to $43.3 million ($0.83 per diluted share) in the same

period of the prior year. Net income in the first nine months of 2006 included $10.4 million ($0.19 per diluted share) in stock-based compensation expense due to the adoption of SFAS No. 123(R).

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Licensing

In May 2006, we amended our license and collaboration agreement with DiagnoCure Corporation. Pursuant to the terms of the amendment (i) we granted exclusive rights to DiagnoCure to develop *in vivo* products for the detection or measurement of PCA3 as a marker for the diagnosis, monitoring or prognosis of prostate cancer, (ii) we granted co-exclusive rights to DiagnoCure to develop fluorescence *in situ* hybridization products for the detection or measurement of PCA3 as a marker for the diagnosis, monitoring or prognosis of prostate cancer, (iii) DiagnoCure agreed to undertake over a twelve-month period the validation of genetic markers that we acquired under our license agreement with Corixa Corporation and we agreed to make monthly payments to DiagnoCure for these services, and (iv) we agreed to a new regulatory timeline regarding our development obligations for an *in vitro* diagnostic assay for PCA3.

In April 2006, we entered into a license agreement with the University of Michigan for exclusive worldwide rights to develop diagnostic tests for recently discovered genetic translocations that had been shown in preliminary studies to be highly specific for prostate cancer tissue. In May 2006, pursuant to the terms of this agreement, we paid a license fee of $0.5 million to the University of Michigan. 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.

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 system based on Qualigen s Food and Drug Administration, or FDA, approved FastPack immunoassay system. If development of this instrument is successful, the new system, 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 a result 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-1 Convertible Preferred Non-Voting Stock convertible into approximately 19.5% of Qualigen s capital stock, on an as converted to common stock basis, as of the purchase date. We may also pay Qualigen up to $3.0 million based on achievement of development milestones under the license agreement and agreed to pay Qualigen royalties on sales of any product we develop under the agreement. We recorded this investment as an intangible asset on a cost basis, and will review the asset for impairment on an ongoing basis.

Product development

In October 2006, the FDA granted marketing clearance for the Procleix Ultrio assay to run on the Procleix enhanced semi-automated system, or eSAS. The Procleix Ultrio assay was approved to screen donated blood, plasma, organs and tissue for HIV-1 and HCV in individual blood donations or in pools of up to 16 blood samples, and to detect the presence of HBV. However, the initial pivotal study for the Procleix Ultrio assay was not designed to, and did not, demonstrate yield, defined as HBV-infected blood donations that are negative based on serology tests for HBV surface antigen and core antibody. Based on discussions with the FDA, we and Novartis will initiate a post-marketing study to demonstrate HBV yield in order to gain a donor-screening claim. We expect this study to begin in early 2007 as the commercial assay becomes available. The Procleix Ultrio assay is approved for commercial blood screening use (including HBV) in many countries outside the United States.

In October 2006, the FDA granted marketing clearance for the APTIMA HIV-1 RNA qualitative assay. The assay may be used as an aid in the diagnosis of acute and primary HIV-1 infection, and to confirm HIV-1 infection in individuals who repeatedly test positive for HIV-1 antibodies. We expect to launch the assay in November 2006 in conjunction with the APTIMA HCV (hepatitis C virus) RNA qualitative assay.

Finally, in October 2006, the FDA granted marketing clearance to run our standalone APTIMA assays for chlamydia and gonorrhea on the fully automated TIGRIS instrument. The two amplified nucleic acid tests, which were previously approved to run on eSAS, detect the microorganisms that cause the most common bacterial sexually transmitted diseases in the United States.

In August 2006, the FDA granted marketing clearance to use the APTIMA Combo 2 assay to test two additional kinds of patient samples for chlamydia and gonorrhea on our fully automated TIGRIS instrument.

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During the second quarter of 2006, two clinical laboratory customers completed validation of TMA assays for PCA3 and PSA, using our analyte specific reagents, or ASRs, and general purpose reagents, or GPRs, and began offering these tests to physicians and reporting patient results, employing a PCA3 to PSA ratio.

In March 2006, we began shipment to Novartis of FDA approved and labeled Procleix West Nile Virus, or WNV, assays for use with eSAS. In April 2006, we submitted to the FDA a prior-approval supplement to our WNV assay Biologics License Application, or BLA, adding the TIGRIS instrument and we submitted an application for 510(k) clearance of the TIGRIS instrument for use with the WNV assay at the same time. In June 2006, we received questions from the FDA regarding our 510(k) application for the TIGRIS instrument. In September 2006, we responded to the FDA s questions presented in a complete review letter we received in late July 2006, which set forth questions regarding the prior-approval supplement to the BLA adding the TIGRIS instrument. Both the BLA supplement and the 510(k) application must be approved before licensed testing with the WNV assay can begin on the TIGRIS instrument. There can be no assurance that such approvals will be received.

In March 2006, in response to FDA comments, we withdrew use of TriPath s liquid Pap transport media from the APTIMA *Chlamydia trachomatis* assay 510(k) application. We are deferring further FDA applications concerning use of our assays with the TriPath media.

In October 2005, the FDA 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. Now that the Procleix Ultrio assay has been granted marketing approval to run on eSAS, we anticipate submitting a supplement to the approved BLA to allow the assay to be performed on the TIGRIS instrument. There can be no assurance 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 substantial 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 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 nine months of 2006, product sales, collaborative research revenues, and royalty and license revenues equaled 91%, 6% and 3%, respectively, of our total revenues of $263.7 million. For the same period in the prior year, product sales, collaborative research revenues and royalty and license revenues equaled 89%, 9%, and 2%, respectively, of our total revenues of $218.0 million.

Product sales

Our primary source of revenue is the sale of clinical diagnostic and blood screening products in the United States. Our clinical diagnostic products include our APTIMA, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. The principal customers for our clinical diagnostics products include large reference laboratories, public health laboratories and hospitals.

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 end-user 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 end-users, 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 after commercialization primarily include manufacturing costs.

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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 the nine months ended September 30, 2006, we recognized $9.2 million as collaborative research revenue, compared to $13.4 million for the same period in the prior year, through our collaboration with Novartis from deliveries of WNV tests on a cost recovery basis. For the first nine months of 2006 and 2005, we recognized $1.0 million and $1.7 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 the first quarter of 2006, upon shipment of FDA approved and labeled product, we changed the recognition of sales of the WNV assay for use on eSAS from collaborative research revenue to product sales.

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 consolidated 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.

Under our 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. Under the terms of the agreement, a milestone payment from Novartis 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.

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 nine month 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 nine months 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.

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During the first nine months of 2006 and 2005, a portion of our blood screening revenues was from sales of TIGRIS instruments to Novartis, totaling approximately $6.6 million in both periods. 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 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.

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 nine months ended September 30, 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, 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 nine months of 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 nine months 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

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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. For the first nine months of 2006, stock-based compensation expense related to stock options and employee stock purchases was $16.2 million, before taxes on earnings. For the nine months ended September 30, 2006 and 2005, stock-based compensation expense related to restricted stock was $1.5 million and $0.3 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-Merton 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. Historically, we determined the expected term of stock options based on Section 16 insider reported data from a select group of peer companies. In May 2006, our stockholders approved an amendment and restatement of The 2003 Incentive Award Plan that decreased the maximum contractual term of our prospective option grants from ten years to seven years. Corresponding with this change, we revised our determination of the expected term of options by applying a weighted-average calculation combining the average life of options that have already been exercised with the estimated life of all unexercised options.

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 nine months of 2006, we reduced stock-based compensation expense to allow for estimated forfeitures based on historical experience. Also, during the third quarter of 2006, we changed our method of applying estimated forfeitures to more accurately reflect the number of options that are expected to vest. The effect of this change in estimate was to increase stock-based compensation expense by $1.0 million, decrease net income by $0.6 million, and decrease diluted earnings per share by $0.01. 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 nine months of 2006.

Results of Operations

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2006	2005	$ Change	% Change	2006	2005	$ Change	% Change
	(in millions, except per share data)							
Statements of income:								
Revenues:								
Product sales	$ 83.5	$ 69.0	$ 14.5	21%	$ 239.8	$ 193.6	$ 46.2	24%
	1.5	6.3	(4.8)	(76)%	14.7	19.4	(4.7)	(24)%

Collaborative research revenue								
Royalty and license revenue	7.3	1.0	6.3	630%	9.2	5.0	4.2	84%
Total revenues	92.3	76.3	16.0	21%	263.7	218.0	45.7	21%
Operating expenses:								
Cost of product sales	23.8	21.4	2.4	11%	74.7	57.2	17.5	31%
Research and development	24.2	17.5	6.7	38%	63.8	53.6	10.2	19%
Marketing and sales	9.5	7.6	1.9	25%	27.6	22.4	5.2	23%
General and administrative	12.8	7.8	5.0	64%	34.1	22.8	11.3	50%
Total operating expenses	70.3	54.3	16.0	29%	200.2	156.0	44.2	28%
Income from operations	22.0	22.0		0%	63.5	62.0	1.5	2%
Total other income, net	1.9	1.3	0.6	46%	5.1	3.4	1.7	50%
Income tax expense	8.8	6.9	1.9	28%	25.3	22.1	3.2	14%
Net income	$ 15.1	$ 16.4	$ (1.3)	(8)%	$ 43.3	$ 43.3	$	%
Net income per share								
Basic	$ 0.29	$ 0.32	$ (0.03)	(9)%	$ 0.84	$ 0.86	$ (0.02)	(2)%
Diluted	$ 0.28	$ 0.31	$ (0.03)	(10)%	$ 0.82	$ 0.83	$ (0.01)	(1)%
Weighted average shares outstanding								
Basic	51.6	50.7			51.4	50.5		
Diluted	53.2	52.5			53.0	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.

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Product sales

Product sales increased 21% in the third quarter and 24% in the first nine months of 2006 from the comparable periods of 2005. During the third quarter of 2006, product sales grew by $14.5 million, compared to the same period in the prior year, primarily due to $9.4 million in higher blood screening assay sales, and $8.1 million in higher APTIMA Combo 2 assay sales, partially offset by a $1.9 million decrease in PACE product sales and a $1.5 million decrease in instrument sales. Blood screening sales represented $40.2 million, or 48% of product sales, in the third quarter of 2006, compared to $32.9 million, or 48% of product sales for the third quarter of 2005. The increase in blood screening sales during the third quarter of 2006 was principally attributed to the U.S commercial launch of our WNV assay.

During the first nine months of 2006, the $46.2 million increase in product sales from the same period in the prior year was primarily attributed to $23.8 million in higher APTIMA Combo 2 assay sales, $23.0 million in higher blood screening assay sales, and $3.3 million in higher instrument sales, partially offset by a $5.4 million decrease in PACE product sales. Blood screening sales represented $114.0 million, or 48% of product sales, in the first nine months of 2006, compared to $89.3 million, or 46% of product sales for the first nine months of 2005. The increase in blood screening sales during the first nine months of 2006 was principally attributed to the U.S commercial launch 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 decreased 76% in the third quarter of 2006 and decreased 24% in the first nine months of 2006 from the comparable periods of 2005. The $4.8 million decrease during the third quarter was primarily the result of a $4.4 million decrease in revenue through our collaboration with Novartis from deliveries of WNV tests on a cost recovery basis (now recorded as product sales) and a $1.2 million decrease in reimbursements for expenses from Novartis for Ultrio and WNV development research and the discontinuation of warehousing fees. These decreases were partially offset by a $0.7 million increase in revenue for reimbursement from one of our industrial partners for certain assay development costs.

The $4.7 million decrease during the first nine months of 2006 was primarily the result of a $4.2 million decrease in revenue through our collaboration with Novartis from deliveries of WNV tests on a cost recovery basis (now recorded as product sales) and a $2.7 million decrease in reimbursements for expenses from Novartis for Ultrio and WNV development research and the discontinuation of warehousing fees. These decreases were partially offset by a $2.0 million increase in revenue for reimbursement from one of our industrial partners for certain assay development costs and a $0.2 million increase in revenue for shipments of dHBV assays and TIGRIS instrument lease revenue from Novartis.

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.

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Royalty and license revenue

Royalty and license revenue increased 630% in the third quarter of 2006 and 84% in the first nine months of 2006 from the comparable periods of 2005. The $6.3 million increase during the third quarter was principally attributed to a $5.0 million increase in license fee revenue from Bayer Corporation, or Bayer, pursuant to the terms of our Settlement Agreement as well as a $1.0 million increase in license revenue from Tosoh Corporation. We received this revenue from Tosoh as a result of expanding the scope of Tosoh s license from us under the terms of a 2004 license agreement, which we were able to effect in light of the Settlement Agreement. Additionally, our royalty revenue increased by $0.3 million during the third quarter from our share of royalties from Novartis, which are based upon its agreement with Laboratory Corporation of America, or LabCorp, for use of Novartis HCV intellectual property for NAT used in screening plasma donations in the United States.

The $4.2 million increase in royalty and license revenue during the first nine months of 2006 was principally attributed to a $5.0 million increase in license fee revenue from Bayer pursuant to the terms of our Settlement Agreement as well as a $1.0 million increase in license revenue from Tosoh as detailed above. Additionally, we received a $0.1 million increase in royalties in the period from Becton Dickinson and $0.2 million in license fee revenues associated with the out-license of hybridization protection assay, or HPA, technology to Alnylam Pharmaceuticals. These increases were partially offset by a $1.9 million decrease in license fee revenue we recognized from bioMérieux s affiliates during the first nine months of 2005, which was based on the selection of targets pursuant to the terms of our September 2004 agreement with bioMérieux, and a $0.4 million decrease in our share of royalties from Novartis, based upon its agreement with LabCorp 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 11% in the third quarter of 2006 and 31% in the first nine months of 2006 from the comparable periods in 2005. The $2.4 million increase during the third quarter was principally attributed to higher APTIMA shipments ($1.2 million), higher provisions for scrap ($0.6 million), commercial launch of our WNV assay ($0.5 million) and an increase in stock-based compensation expense ($0.7 million), partially offset by favorable production variances ($0.6 million).

The $17.5 million increase in cost of product sales during the first nine months of 2006 was primarily due to $8.2 million of higher blood screening product shipments (including commercial launch of our WNV assay and international growth of our Ultrio assay), increased sales of instruments and spare parts ($4.5 million), higher APTIMA shipments ($3.9 million) and higher provisions for scrap ($2.5 million) related to date expiration of certain oligonucleotide raw material, partially offset by favorable production variances ($1.7 million).

Our gross profit margin on product sales increased to 71.5% in the third quarter of 2006, and decreased to 68.8% in the first nine months of 2006, from 69.0% and 70.4%, respectively, in the comparable periods of 2005. The increase in gross margin percentage during the third quarter was principally attributed to increased sales of APTIMA and blood screening products, including commercial launch of our WNV assay and reduced instrument sales.

The decrease in gross profit margin percentage during the first nine months of 2006 was primarily due 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 provisions for scrap expense as discussed above.

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 our blood screening customers requirements for smaller pool sizes or ultimately individual donor testing of blood samples will result in lower gross margin percentages, as additional tests are required to deliver the sample results. We are not able to accurately predict the timing and extent to which our gross margin percentage will be negatively affected as a result of smaller pool sizes or individual donor testing. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion has led and will lead to lower gross margin percentages.

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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 38% in the third quarter and 19% in the first nine months of 2006 from the comparable periods of 2005. The $6.7 million increase during the third quarter of 2006 was primarily due to an increase in stock-based compensation expense ($2.2 million), increases in salaries, benefits, and other personnel related expenses ($2.5 million), due principally to increased personnel, and an increase in the purchase of HPV development lot materials ($1.3 million).

The $10.2 million increase in R&D spending during the first nine months of 2006 was primarily due to an increase in stock-based compensation expense ($6.1 million), increases in salaries, benefits, and other personnel related expenses ($4.1 million), due principally to increased personnel, and increased spending on outside services ($1.8 million), partially offset by reductions in clinical trials for blood screening products ($0.5 million) and professional fees ($1.1 million).

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased 25% in the third quarter and 23% in the first nine months of 2006 from the comparable periods of 2005. The $1.9 million increase during the third quarter of 2006 was primarily due to an increase in stock-based compensation expense ($0.9 million), increases in salaries, benefits, commissions and travel related expenses ($0.8 million) due principally to increased personnel, and an increase in spending for professional fees ($0.2 million).

The $5.2 million increase in marketing and sales expenses during the first nine months of 2006 was primarily due to an increase in stock-based compensation expense ($2.4 million), increases in salaries, benefits, commissions and travel related expenses ($2.3 million) due principally to increased personnel, and an increase in spending for professional fees ($0.6 million).

General and administrative

Our general and administrative, or G&A, expenses include personnel costs for executive, 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. General and administrative expenses increased 64% in the third quarter and 50% in the first nine months of 2006 from the comparable periods of 2005. The $5.0 million increase during the third quarter of 2006 was primarily the result of an increase in stock-based compensation expense ($3.0 million), increases in professional fees ($1.3 million) primarily due to our $2.0 million payment to our outside litigation counsel in connection with the Bayer settlement, and an increase in salaries, benefits, and other personnel related expenses ($0.7 million) due principally to increased personnel.

The $11.3 million increase in G&A expenses during the first nine months of 2006 was primarily the result of an increase in stock-based compensation expense ($7.4 million), an increase in salaries, benefits and other personnel related expenses ($1.5 million) due principally to increased personnel, and an increase in professional fees ($2.3 million) due to higher legal fees associated with our two patent infringement lawsuits against Bayer and our $2.0 million payment during the third quarter to our outside litigation counsel in connection with the Bayer settlement.

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 in total other income during the third quarter, and the $1.7 million increase in the first nine months of 2006, from the comparable periods of 2005, were both 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, partially offset by realized foreign currency exchange losses.

Income tax expense

Income tax expense increased to $8.8 million, or 36.8% of pretax income, in the third quarter of 2006, from $6.9 million, or 29.6% of pretax income, in the same period of the prior year. During the first nine months of 2006, income tax expense increased to $25.3 million, or 36.9% of pretax income, from $22.1 million, or 33.8% of pretax income, in the same period of the prior year. The increase in our effective tax rate was principally attributed to additional research and development tax credits recognized during the third quarter of the prior year, expiration of the

federal research and development credit in 2006 and our 2006 adoption of SFAS No. 123(R), partially offset by benefits from increases in our tax exempt interest income.

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Liquidity and Capital Resources

(In thousands)

	September 30, 2006	December 31, 2005
Cash, cash equivalents and short-term investments	$ 271,520	$ 220,288
Working capital	$ 323,870	$ 262,659
Current ratio	8:1	6:1

	Nine Months Ended September 30,		
	2006	2005	$ Change
Cash provided by (used in):			
Operating activities	$ 72,041	$ 68,181	$ 3,860
Investing activities	(70,109)	(61,683)	(8,426)
Financing activities	27,321	13,963	13,358
Purchases of property, plant and equipment (included in investing activities above)	$ (40,126)	$ (29,894)	$ (10,232)

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 September 30, 2006, we had $271.5 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 nine months of 2006 compared to the same period of the prior year was primarily due 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 from 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, decreases in our deferred contract revenue balances, along with the reclassification of stock option income tax benefits from operating to financing activities in accordance with SFAS No. 123(R).

The $8.4 million increase in net cash used in investing activities during the first nine months of 2006 compared to the same period of the prior year included a $10.2 million increase in capital expenditures and a $13.5 million increase in purchases (net of sales) of short-term investments, partially offset by a $14.8 million net decrease in license, manufacturing access fees and 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. Our decrease in license, manufacturing access fees and investments in the first nine months of 2006 was due to a $20.0 million manufacturing fee paid to Roche in May 2005, partially offset by our $7.0 million equity investment in Qualigen in April 2006.

The $13.4 million increase in net cash provided by financing activities during the first nine months of 2006 compared to the same period of the prior year was principally attributed to a $4.9 million increase in proceeds from the exercise of stock options, a $0.3 million increase in the net proceeds from ESPP purchases, and $8.2 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 September 30, 2006, we were in compliance with all covenants.

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In May 2006, we completed construction of an additional building on our main San Diego campus. This new building consists of a 292,000 square foot shell, with approximately 214,000 square feet built-out with interior improvements in the first phase. The remaining expansion space can be used to accommodate future growth. First phase construction costs were approximately $46 million. These costs were capitalized as incurred and depreciation commenced upon our move-in during May 2006.

We implemented a new ERP system that cost approximately $4.9 million in 2004. We incurred $3.3 million and $0.8 million in additional costs during 2005 and the first nine months of 2006, respectively. We expect to incur up to $2.8 million in 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 September 30, 2006 were as follows (in thousands):

	Total	2006	2007	2008	2009	Thereafter
Operating leases (1)	$ 1,383	$ 283	$ 863	$ 167	$ 70	$
Material purchase commitments (2)	11,699	5,803	5,896			
Collaborative commitments (3)	17,869	3,269	3,050	10,400	1,150	
Total (4)	$ 30,951	$ 9,355	$ 9,809	$ 10,567	$ 1,220	$

(1) Reflects obligations on facilities under operating leases in place as of September 30, 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 $10.5 million expected to be purchased for

TIGRIS instruments in 2006 and 2007, we anticipate that approximately $5.9 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 $8.5 million in milestone payments, plus royalties on net sales of any products using specified technology.

(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 typically dependent upon when certain key employees retire or otherwise leave the Company. At this time, we cannot reasonably predict when these events may occur.

Our primary short-term needs for capital, which are subject to change, are for research and development of new products, costs related to commercialization of our 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.

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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.

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	
Additional Authorized	3,000*				
Grants	(1,709)	1,421	50.20	143**	2
Exercises		(760)	22.85		(2)
Cancellations	200***	(182)	39.69	(12)	
September 30, 2006	2,431	6,433	$ 34.60	303****	

* In May 2006, the Company s stockholders approved an amendment and restatement of The 2003 Incentive Award Plan (the 2003 Plan) that increased the

aggregate number of shares of common stock authorized for issuance by 3,000,000 shares.

** Actual number of restricted shares granted was 142,800, however, pursuant to the terms of the 2003 Plan, as amended, the number of shares reserved for issuance has been reduced by 285,600, reflecting a reduction of two shares for each share of restricted stock granted after May 17, 2006 (in lieu of one share under the 2003 Plan prior to its amendment).

*** Includes cancellation of 6,000 restricted shares that were granted after May 17, 2006, reflecting two shares for each restricted share canceled.

**** Includes 80,000 shares of Deferred Issuance

Restricted Stock and approximately 222,500 shares of Restricted Stock as of September 30, 2006.

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

	Exercisable		Unexercisable		Total	
As of September 30, 2006	**Shares**	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**
In-the-money	2,981	$ 24.17	1,846	$ 38.01	4,827	$ 29.39
Out-of-the money(1)	89	49.80	1,517	50.04	1,606	50.03
Total options outstanding	3,070		3,363		6,433	

(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, $46.89, at the close of business on September 30, 2006.

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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 and market 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 $4.2 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 in the United Kingdom 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. Generally, 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 September 30, 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 our international blood screening product sales during the first nine months of 2006, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $4.1 million annually. We believe that our business operations are not exposed to market risk relating to commodity price risk.

Item 4. Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the quarter ended September 30, 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 changes in our internal control over financial reporting during the quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 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. 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. We have marked with an asterisk those risk factors that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2005.

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 new blood screening products and some of our clinical diagnostic products 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 43% of our total revenues for the first nine months 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.

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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. We recently entered into a settlement agreement with Bayer regarding this arbitration and the patent litigation between the parties. Under the terms of the settlement agreement, the parties submitted a stipulated final award adopting the arbitrator s prior interim and supplemental awards, except that Bayer was no longer obligated to reimburse us $2.0 million for legal expenses previously awarded in the arbitrator s June 5, 2005 Interim Award. The arbitrator determined that the collaboration agreement shall be terminated, as we requested, except as to the qualitative hepatitis C virus (HCV) assays and as to quantitative Analyte Specific Reagents (ASR) for HCV. Bayer retains the co-exclusive right to distribute the qualitative HCV tests and the exclusive right to distribute the quantitative HCV ASR. As a result of a termination of the agreement, we re-acquired the right to develop and market future viral assays that had been previously reserved for Bayer. The arbitrator s March 3, 2006 supplemental award determined that we are not obligated to pay Bayer an initial license fee in connection with the sale of the qualitative human immunodeficiency virus and HCV assays and that we will be required to pay running sales royalties, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents. On June 29, 2006, Bayer announced that it had entered into an agreement to sell its diagnostics division to Siemens AG. The agreement is subject to regulatory approval. We do not know what effect, if any, the sale of Bayer s diagnostics division to Siemens will have on the remaining elements of our collaboration with Bayer for viral diagnostic products.

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 those 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 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. The collaboration agreement is also subject to termination prior to expiration upon a material breach by either party to the agreement.

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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 Food and Drug Administration (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 enhanced semi-automated system (eSAS). The FDA made this determination in response to our 510(k) application for the TIGRIS instrument for blood screening. More recently, on July 19, 2006, we received a complete review letter from the FDA setting forth questions regarding the prior-approval supplement to our BLA for the West Nile Virus (WNV) assay, adding the TIGRIS instrument. There can be no assurance that the 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.

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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 (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 some 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, (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.

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Our gross profit margin percentage on the sale of blood screening assays will 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 will decrease upon the adoption of individual donor testing. We are not able to predict accurately the extent to which our gross profit margin percentage will 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 49% of our total revenues for the first nine months 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 nine months ended September 30, 2006. In addition, Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated and various state and city public health agencies accounted for an aggregate of 20% of our total revenues for the first nine months 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 420 United States and foreign patents covering our products and technologies as of September 30, 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.

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 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, third parties may develop competing products based on technology that is not covered by our patents.

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

The diagnostic products industry has a history of patent and other intellectual property litigation, and we 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 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. Additionally, we hold certain rights in the blood screening and clinical diagnostics fields under patents issued to Chiron (now Novartis) 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.

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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 September 30, 2006, we had approximately $224.1 million of long-lived assets, including $19.1 million of capitalized software relating to our TIGRIS instrument, goodwill of $18.6 million, a $2.5 million investment in Molecular Profiling Institute, Inc., a $7.0 million investment in Qualigen, Inc., and $46.6 million of capitalized license and manufacturing access fees, patents and purchased intangibles. Additionally, we had $66.4 million of land and buildings, $13.9 million of leasehold improvements, $1.0 million of construction in-progress and $49.0 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 a new instrument platform, if any, in turn would require the modification of existing assays for use with the new instrument, and additional regulatory approvals.

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 have experienced delays in FDA clearance for our TIGRIS instrument for blood screening with the Procleix Ultrio assay and with respect to our regulatory application to run our previously approved WNV assay on the TIGRIS instrument. 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 nucleic acid testing (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 industrial testing markets. The process of successfully developing products for application in these 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 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.

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

In recent years, we have incurred significant costs in connection with the development of our blood screening 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 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 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.

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If we or our contract manufacturers are unable to manufacture our products in sufficient quantities, on a timely basis, at acceptable costs 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.

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. Our assay products incorporate complex biochemical reagents and our instruments comprise complex hardware and software. We have in the past voluntarily recalled products, which, in each case, required us to identify and correct the problem. Our products may be subject to additional recalls in the future. Although none of our past product recalls have had a material adverse impact on our business, a future government-mandated recall, or a voluntary recall by us, could divert managerial and financial resources, could be more difficult and costly to correct, could result in the suspension of sales of our products, and could 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 23% of our total revenues for the first nine months 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 81% of our international revenues for the first nine months 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% of our international sales for the first nine months of 2006 and 5% of our international sales for 2005.

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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,

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 hepatitis A virus (HAV), and parvo B19, as well as HBV, 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 will result in lower gross margin percentages, as additional tests are required to deliver the sample results. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion has led and will lead to lower gross margin percentages.

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.

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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 that 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. 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.

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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.

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 recently entered into an amendment to our rights plan to terminate the plan effective November 30, 2006. Prior to the effective date, our rights plan could discourage, delay or prevent an acquisition of us under certain circumstances. The rights plan currently 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.

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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;

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 Financial Accounting Standards Board 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 Accounting Principles Board No. 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 by $10.4 million ($0.19 per diluted share) for the first nine months of 2006 and will negatively impact our future earnings.

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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 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.

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.

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Item 6. Exhibits

Exhibit Number	Description
2.1(1)	Separation and Distribution Agreement, dated and effective as of May 24, 2002, and amended and restated as of August 6, 2002, by and between Chugai Pharmaceutical Co., Ltd. and Gen-Probe Incorporated.
3.1(1)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(5)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(1)	Form of Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(5)	Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)	Specimen common stock certificate.
4.2(2)	Rights Agreement, dated as of September 16, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C.
4.3(3)	First Amendment to Rights Agreement, dated October 9, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC.
4.4(4)	Second Amendment to Rights Agreement, dated November 20, 2003.
4.5	Third Amendment to Rights Agreement, dated October 3, 2006.
10.96 *	Settlement Agreement dated August 1, 2006 by and among Gen-Probe Incorporated, Bayer HealthCare LLC and Bayer Corporation.
31.1	Certification dated November 1, 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 November 1, 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 November 1, 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 November 1, 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.

*

Gen-Probe has requested confidential treatment with respect to certain portions of this exhibit.

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

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

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

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

(5) Incorporated by reference to Gen-Probe s

Quarterly Report on Form 10-Q filed with the SEC on August 9, 2004.

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SIGNATURES

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

DATE: November 1, 2006 By: /s/ Henry L. Nordhoff

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

DATE: November 1, 2006 By: /s/ Herm Rosenman

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