GEN PROBE INC
Form 10-Q
November 06, 2007

Table of Contents

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

(Mark One)

þ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended September 30, 2007

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, 2007, there were 53,796,801 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

GEN-PROBE INCORPORATED
TABLE OF CONTENTS
FORM 10-Q

Table of Contents

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

	September 30, 2007 (unaudited)	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,888	$ 87,905
Short-term investments	328,185	202,008
Trade accounts receivable, net of allowance for doubtful accounts of $750 and $670 at September 30, 2007 and December 31, 2006, respectively	38,235	25,880
Accounts receivable other	5,166	1,646
Inventories	49,186	52,056
Deferred income tax short term	6,673	7,247
Prepaid income tax	16,229	
Prepaid expenses	17,874	11,362
Other current assets	5,374	2,583
Total current assets	533,810	390,687
Property, plant and equipment, net	131,245	134,614
Capitalized software	16,552	18,437
Goodwill	18,621	18,621
Deferred income tax long term	2,064	2,064
License, manufacturing access fees and other assets	58,947	59,416
Total assets	$ 761,239	$ 623,839
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 14,696	$ 13,586
Accrued salaries and employee benefits	23,055	16,723
Other accrued expenses	8,683	3,320
Income tax payable	732	14,075
Deferred income tax short term	103	
Deferred revenue	1,623	921
Total current liabilities	48,892	48,625
Non-current income tax payable	4,766	
Deferred income tax long term	360	
Deferred revenue	3,167	3,667
Deferred rent	40	128
Deferred compensation plan liabilities	1,755	1,211
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, 53,718,400 and 52,233,656 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively		5		5
Additional paid-in capital		400,883		334,184
Accumulated other comprehensive income (loss)		581		(5)
Retained earnings		300,790		236,024
Total stockholders equity		702,259		570,208
Total liabilities and stockholders equity	$	761,239	$	623,839

See accompanying notes to consolidated financial statements.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenues:				
Product sales	$ 97,402	$ 83,470	$ 278,451	$ 239,811
Collaborative research revenue	3,118	1,470	11,239	14,743
Royalty and license revenue	1,213	7,287	14,375	9,151
Total revenues	101,733	92,227	304,065	263,705
Operating expenses:				
Cost of product sales	31,810	24,298	91,148	76,207
Research and development	27,582	24,178	72,813	63,833
Marketing and sales	9,651	9,526	28,580	27,533
General and administrative	11,380	12,748	34,742	34,104
Total operating expenses	80,423	70,750	227,283	201,677
Income from operations	21,310	21,477	76,782	62,028
Total other income, net	3,333	1,921	8,610	5,081
Income before income tax	24,643	23,398	85,392	67,109
Income tax expense	7,392	8,587	19,664	24,745
Net income	$ 17,251	$ 14,811	$ 65,728	$ 42,364
Net income per share:				
Basic	$ 0.32	$ 0.29	$ 1.25	$ 0.82
Diluted	$ 0.31	$ 0.28	$ 1.21	$ 0.80
Weighted average shares outstanding:				
Basic	53,221	51,638	52,661	51,407
Diluted	54,857	53,180	54,210	53,001

See accompanying notes to consolidated financial statements.

Table of Contents

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

	Nine Months Ended September 30,	
	2007	**2006**
Operating activities		
Net income	$ 65,728	$ 42,364
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	25,518	19,752
Stock-based compensation charges	14,487	17,755
Stock option income tax benefits	2,031	111
Excess tax benefit from employee stock options	(13,055)	(8,232)
Loss on disposal of property and equipment	202	4
Changes in assets and liabilities:		
Accounts receivable	(15,861)	7,550
Inventories	2,660	(5,338)
Prepaid expenses	(6,538)	(682)
Other current assets	(2,756)	507
Other long term assets	(930)	(1,305)
Accounts payable	1,116	(3,103)
Accrued salaries and employee benefits	6,328	2,821
Other accrued expenses	5,343	624
Income tax payable	(14,544)	2,037
Deferred revenue	202	(3,975)
Deferred income tax	794	645
Deferred rent	(88)	(87)
Deferred compensation plan liabilities	544	593
Net cash provided by operating activities	71,181	72,041
Investing activities		
Proceeds from sales and maturities of short-term investments	57,391	83,641
Purchases of short-term investments	(182,449)	(104,163)
Purchases of property, plant and equipment	(17,674)	(40,126)
Capitalization of intangible assets, including license fees	(2,127)	(2,245)
Investment in Qualigen		(6,993)
Other assets	(334)	(223)
Net cash used in investing activities	(145,193)	(70,109)
Financing activities		
Repurchase and retirement of restricted stock for payment of taxes	(1,020)	
Excess tax benefit from employee stock options	13,055	8,232
Proceeds from issuance of common stock	40,677	19,089
Net cash provided by financing activities	52,712	27,321

Effect of exchange rate changes on cash and cash equivalents	283	485
Net (decrease)/increase in cash and cash equivalents	(21,017)	29,738
Cash and cash equivalents at the beginning of period	87,905	32,328
Cash and cash equivalents at the end of period	$ 66,888	$ 62,066

See accompanying notes to consolidated financial statements.

Table of Contents

Notes to the Consolidated Financial Statements (unaudited)

Note 1 Basis of presentation

The accompanying interim consolidated financial statements of Gen-Probe Incorporated (Gen-Probe or the Company) at September 30, 2007, and for the three and nine month periods ended September 30, 2007 and 2006, 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 consolidated 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, 2007.

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, 2006.

Note 2 Summary of significant accounting policies

Recent accounting pronouncements

In September 2006, the Securities and Exchange Commission (SEC) released Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, (SAB No. 108). SAB No. 108, which is effective for fiscal years ending after November 15, 2006, provides guidance on how the effects of prior year uncorrected misstatements, previously deemed to be immaterial, must be considered and adjusted during the current year. The Company adopted this statement effective January 1, 2006, which resulted in a recast of its financial results for the first nine months of 2006. The details are more fully discussed in Note 1 of the Company s Annual Report on Form 10-K for the year ended December 31, 2006.

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 (FIN No. 48) Accounting for Uncertainty in Income Taxes an interpretation of Statement of Financial Accounting Standards (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 No. 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The Company adopted this statement effective January 1, 2007, which resulted in an adjustment of $962,000 for the net impact of the change in guidance. The adjustment was accounted for as a reduction in the beginning balance of retained earnings and an increase in the beginning balance of net tax liabilities. The Company does not anticipate that the adoption of FIN No. 48 will have a material effect on its statements of income and effective tax rate in future periods.

Contingencies

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

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales & Service, Inc., Gen-Probe International, Inc., Gen-Probe UK Limited (GP UK Limited) and Molecular Light Technology Limited (MLT) and its subsidiaries. Prior to the second quarter of 2007, MLT and its subsidiaries were consolidated into the Company s financial statements one month in arrears. During the second quarter of 2007, as part of MLT s integration onto the Company s enterprise resource planning (ERP) system, the lag time between reporting periods was eliminated. The effect of this change was immaterial to the Company s financial statements. All intercompany transactions and balances have been eliminated in consolidation.

Table of Contents

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, license and manufacturing access fees, income tax, 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

Share-based payments

On January 1, 2006, the Company adopted SFAS No. 123(R), Share-Based Payment. 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. Stock-based compensation expense recognized is based on the value of the portion of stock-based payment awards that is ultimately expected to vest, which coincides with the award holder s requisite service period. Certain of these costs are capitalized into inventory on the Company s balance sheet, and generally are recognized as an expense when the related products are sold.

The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes-Merton model is affected by the Company s stock price and the implied volatility on its traded options, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and the Company s expected stock price volatility over the term of the awards. The Company s stock options and the option component of the Company s Employee Stock Purchase Plan (ESPP) shares have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

The Company used the following weighted average assumptions (annualized percentages) to estimate the fair value of options granted and the shares purchased under the Company s stock option plans and ESPP for the three and nine month periods ended September 30, 2007 and 2006:

	Stock Option Plans				ESPP			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006	2007	2006	2007	2006
Risk-free interest rate	4.7%	4.8%	4.7%	4.8%	5.0%	5.0%	5.0%	4.4%
Volatility	37%	42%	36%	42%	29%	38%	29%	40%
Dividend yield								
Expected term (years)	4.2	4.2	4.2	4.5	0.5	0.5	0.5	0.5
Resulting average	$ 22.42	$ 19.87	$ 21.13	$ 20.93	$ 13.82	$ 13.48	$ 12.89	$ 12.99

fair value

Table of Contents

The Company s unrecognized compensation expense, before income tax and adjusted for estimated forfeitures, related to outstanding unvested stock-based awards was approximately as follows (in thousands, except number of years):

Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of September 30, 2007
Options	1.7	$ 42,016
ESPP	0.2	76
Restricted stock	1.7	12,459
Deferred Issuance Restricted Stock	1.5	2,371
		$ 56,922

At September 30, 2007, the Company had outstanding 305,395 shares of unvested restricted stock and Deferred Issuance Restricted Stock from awards that had a weighted average grant date fair value of $53.09 per share. The fair value of the 44,041 shares of restricted stock and Deferred Issuance Restricted Stock from awards that vested during the first nine months of 2007 was approximately $2,048,000.

Impact 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 statement of income in accordance with SFAS No. 123(R) for the three and nine month periods ended September 30, 2007 and 2006 (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Cost of product sales	$ 663	$ 743	$ 2,345	$ 1,366
Research and development	1,206	2,024	3,076	5,698
Marketing and sales	581	863	1,552	2,335
General and administrative	1,755	2,749	4,950	6,755
Reduction of operating income before income tax	4,205	6,379	11,923	16,154
Income tax benefit	(1,012)	(2,331)	(4,441)	(5,782)
Reduction of net income	$ 3,193	$ 4,048	$ 7,482	$ 10,372
Reduction of net income per share:				
Basic	$ 0.06	$ 0.08	$ 0.14	$ 0.20
Diluted	$ 0.06	$ 0.08	$ 0.14	$ 0.19

Note 4 Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share and SFAS No. 123(R). 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.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income	$ 17,251	$ 14,811	$ 65,728	$ 42,364
Weighted average shares outstanding Basic	53,221	51,638	52,661	51,407
Effect of dilutive common stock options outstanding	1,636	1,542	1,549	1,594
Weighted average shares outstanding Diluted	54,857	53,180	54,210	53,001
Net income per share:				
Basic	$ 0.32	$ 0.29	$ 1.25	$ 0.82
Diluted	$ 0.31	$ 0.28	$ 1.21	$ 0.80

Dilutive securities include common stock options subject to vesting. Potentially dilutive securities totaling 1,493,973 and 1,437,857 shares for the three month periods ended September 30, 2007 and 2006, respectively, and 1,507,776 and 1,149,091 shares for the nine month periods ended September 30, 2007 and 2006, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Note 5 Comprehensive income

In accordance with SFAS No. 130, Reporting Comprehensive Income, all components of comprehensive income, including net income, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income (loss), which includes certain changes in stockholders equity such as foreign currency translation of the Company s wholly owned subsidiaries financial statements and unrealized gains and losses on their available-for-sale securities, are reported, net of their related tax effect, to arrive at comprehensive income.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income	$ 17,251	$ 14,811	$ 65,728	$ 42,364
Change in unrealized gain (loss) on investments	1,466	1,023	1,015	462
Foreign currency translation adjustment	(440)	(68)	(429)	1,050
Other comprehensive income, net	1,026	955	586	1,512
Comprehensive income	$ 18,277	$ 15,766	$ 66,314	$ 43,876

Table of Contents

Note 6 Balance sheet information

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

Inventories

	September 30, 2007	December 31, 2006
Raw materials and supplies	$ 8,205	$ 9,479
Work in process	22,641	25,018
Finished goods	18,340	17,559
	$ 49,186	$ 52,056

Property, plant and equipment

	September 30, 2007	December 31, 2006
Land	$ 13,862	$ 13,862
Building	69,946	70,928
Machinery and equipment	137,518	128,572
Tenant improvements	31,529	28,185
Furniture and fixtures	16,037	15,995
Construction in-progress	479	618
Property, plant and equipment (at cost)	269,371	258,160
Less accumulated depreciation and amortization	(138,126)	(123,546)
Property, plant and equipment (net)	$ 131,245	$ 134,614

License, manufacturing access fees and other assets

	September 30, 2007	December 31, 2006
Patents	$ 17,217	$ 16,689
Purchased intangible assets	33,636	33,636
License and manufacturing access fees	53,326	51,726
Investment in Molecular Profiling Institute, Inc.	2,500	2,500
Investment in Qualigen, Inc.	6,993	6,993
Other assets	3,220	2,293
	116,892	113,837
Less accumulated amortization	(57,945)	(54,421)
	$ 58,947	$ 59,416

Note 7 Short-term investments

The following is a summary of short-term investments as of September 30, 2007 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal securities	$ 326,245	$ 909	$ (376)	$ 326,778
Foreign debt securities	1,407			1,407
Total short-term investments	$ 327,652	$ 909	$ (376)	$ 328,185

Table of Contents

The following table shows the gross unrealized losses and estimated 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, 2007 (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Municipal securities	$ 25,810	$ (78)	$ 81,815	$ (298)
Foreign debt securities				
Total short-term investments	$ 25,810	$ (78)	$ 81,815	$ (298)

The unrealized losses on the Company s investments in municipal securities were caused by market interest rate increases. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost of the investment. The Company does not consider its investments in municipal securities to be other-than-temporarily impaired at September 30, 2007, since the Company has the ability and intent to hold those investments until a recovery of fair value, which may be at maturity. There were less than $1,000 in realized gains from the sale of short-term investments for the three and nine month periods ended September 30, 2007 and 2006. Gross realized losses from the sale of short-term investments were $13,000 and $48,000 for the three month periods ended September 30, 2007 and 2006, respectively, and $13,000 and $69,000 for the nine month periods ended September 30, 2007 and 2006, respectively.

Note 8 Income tax

Effective January 1, 2007, the Company adopted FIN No. 48. In accordance with the transition guidance provided by FIN No. 48, the Company increased its accrual for unrecognized tax benefits, principally related to research tax credits, by adjusting for the net cumulative impact of the change in guidance, which was $962,000. The adjustment was accounted for as a reduction in the beginning balance of retained earnings and an increase in the beginning balance of net tax liabilities. As of January 1, 2007, including the FIN No. 48 cumulative adjustment, the Company had total gross unrecognized tax benefits of $17,512,000. The amount of unrecognized tax benefits (net of the federal benefit for state taxes) that would favorably affect the Company s effective income tax rate, if recognized, was $15,260,000.

During the second quarter of 2007, a U.S. federal audit of the Company s 2003 and 2004 tax returns was completed. As a result of this audit, previously unrecognized tax benefits of $9,481,000 were recognized. The completion of the audit, including reversal of accrued interest, resulted in an $8,736,000 benefit that favorably affected the Company s effective tax rate. As of September 30, 2007, the Company had total gross unrecognized tax benefits of approximately $9,157,000. The amount of unrecognized tax benefits (net of the federal benefit for state taxes) that would favorably affect the Company s effective income tax rate, if recognized, was $6,612,000.

The Company estimates that its accrual for unrecognized tax benefits will decrease between $2,500,000 to $2,700,000 during the next twelve months as a result of tax audits expected to be completed during this period. The unrecognized tax benefits generally relate to areas of tax law, including research tax credits, where the determination of an allowable benefit is highly subjective.

The Company s California tax returns for the 2003 and 2004 tax years are currently under audit. Material filings subject to future examination are the Company s U.S. federal and California returns filed for the 2005 and 2006 tax years.

It is the Company s practice to include interest and penalties that relate to income tax matters as a component of income tax expense. Including the cumulative effect of adopting FIN No. 48, $2,157,000 of interest and $0 of penalties were accrued as of January 1, 2007. As of September 30, 2007, the accrued interest balance was $255,000.

Note 9 Stockholders equity

Stock options

The Company s stock option program is a broad-based, long-term retention program that is intended to attract and retain talented employees and directors and to align stockholder and employee interests. Substantially all of the Company s full-time employees have historically participated in the Company s stock option program.

Table of Contents

A summary of the Company s stock option activity for all option plans is as follows (in thousands, except per share data and number of years):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2006	6,300	$ 34.99		
Granted	1,054	58.12		
Exercised	(1,350)	28.85		
Cancelled	(338)	44.29		
Outstanding at September 30, 2007	5,666	40.13	7.4	$ 150,268
Exercisable at September 30, 2007	3,022	$ 30.90	6.2	$ 108,353

The Company defines in-the-money options at September 30, 2007 as options that had exercise prices that were lower than the $66.58 closing market price of its common stock at that date. The aggregate intrinsic value of options outstanding at September 30, 2007 is calculated as the difference between the exercise price of the underlying options and the market price of the Company s common stock for the 3,021,758 shares that were in-the-money at that date. The total intrinsic value of options exercised during the first nine months of 2007 was $39,312,000, determined as of the exercise dates. The total fair value (using the Black-Scholes-Merton Model) of shares vested during the first nine months of 2007 was $19,337,000. The Company also had 80,000 shares of Deferred Issuance Restricted Stock awards and 259,980 shares of restricted stock outstanding as of September 30, 2007 that have not been reflected in the table above.

Additional information about stock options outstanding at September 30, 2007 with exercise prices less than or above $66.58, the closing price of the Company s common stock as of September 30, 2007, is as follows (in thousands, except per share data):

	Exercisable		Unexercisable		Total	
As of September 30, 2007	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
In-the-Money	3,022	$ 30.90	2,644	$ 50.73	5,666	$ 40.13
Out-of-the-Money						
Total Options Outstanding	3,022		2,644		5,666	

A summary of the Company s unvested stock options at September 30, 2007, including the associated fair value of the awards using the Black-Scholes-Merton Model, and changes during the nine months then ended, is as follows (in thousands, except per share data and number of years):

	Weighted Average Remaining

	Number of Shares		Weighted Average Grant-Date Fair Value	Contractual Life (Years)
Non-vested at December 31, 2006	2,959	$	19.51	
Granted	1,054		21.13	
Vested	(1,035)		18.69	
Forfeited	(334)		19.39	
Non-vested at September 30, 2007	2,644	$	20.62	1.4

Table of Contents

Changes in stockholders equity for the nine months ended September 30, 2007 were as follows (in thousands):

Balance at December 31, 2006	$ 570,208
Net income	65,728
Cumulative effect adjustment upon adoption of FIN No. 48	(962)
Other comprehensive income, net	586
Net proceeds from the issuance of common stock	38,937
Purchase of common shares through ESPP	1,740
Purchase of common stock by board members	98
Cancellation of restricted stock awards	(260)
Repurchase and retirement of restricted stock for payment of taxes	(1,020)
Stock-based compensation expense restricted stock	2,726
Stock-based compensation expense all other	11,923
Stock-based compensation net capitalized to inventory	(500)
Tax benefit from the exercise of stock options	13,055
Balance at September 30, 2007	$ 702,259

Note 10 Litigation

The Company is a party to the following litigation and may be involved in other litigation in the ordinary course of business. The Company intends to vigorously defend its interests in this matter. The Company expects that the resolution of this matter will not have a material adverse effect on its business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

Digene Corporation

In December 2006, Digene Corporation (Digene) filed a demand for binding arbitration against F. Hoffman-La Roche Ltd. and Roche Molecular Systems, Inc. (collectively, Roche) with the International Centre for Dispute Resolution (ICDR) of the American Arbitration Association in New York. Digene s arbitration demand challenges the validity of the February 2005 supply and purchase agreement between the Company and Roche. Under the supply and purchase agreement, Roche manufactures and supplies the Company with human papillomavirus (HPV) oligonucleotide products. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting the Company an improper sublicense and seeks a determination that the supply and purchase agreement is null and void.

On July 13, 2007, the ICDR arbitrators granted the Company s petition to join the arbitration. On August 27, 2007, Digene filed an amended arbitration demand and asserted a claim against the Company for tortious interference with the cross-license agreement. The arbitration hearing in this matter has been set for October 2008.

On December 8, 2006, the Company filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a declaratory judgment that the supply and purchase agreement was valid and did not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit the Company to join the arbitration, the San Diego County Superior Court entered judgment dismissing the Company s complaint.

The Company believes that the supply and purchase agreement is valid and that its purchases of HPV oligonucleotide products under the supply and purchase agreement are and will be in accordance with applicable law. However, there can be no assurance that the matter will be resolved in favor of the Company.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a safe harbor for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, intends, estimates, could, should, would, continue, seeks 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, 2007 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, 2006 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, 2006. 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 quarterly report and in our Annual Report on Form 10-K for the year ended December 31, 2006.

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 24 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 sustained growth in both revenues and earnings due to the success of our clinical diagnostic products for sexually transmitted diseases, or STDs, and our blood screening products that are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, hepatitis C virus, or HCV, hepatitis B virus, or HBV, and West Nile Virus, or WNV. Under our collaboration agreement with Novartis Vaccines and Diagnostics, Inc., or Novartis, formerly known as Chiron Corporation, 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.

We are currently developing future nucleic acid probe-based products that we hope to introduce in the clinical diagnostic, blood screening and industrial microbiology testing markets, including products for the detection of human papillomavirus, or HPV, and for measuring markers for prostate cancer. We are also developing instrumentation and software designed specifically for performing our NAT assays, including a new instrument platform designed for low to mid-volume customers.

Recent Events

Financial Results

Product sales for the third quarter of 2007 were $97.4 million, compared to $83.5 million in the same period of the prior year, an increase of 17%. Total revenues for the third quarter of 2007 were $101.7 million, compared to $92.3 million in the same period of the prior year, an increase of 10%. Net income for the third quarter of 2007 was $17.2 million ($0.31 per diluted share), compared to $14.8 million ($0.28 per diluted share) in the same period of the prior year, an increase of 16%.

Product sales for the first nine months of 2007 were $278.5 million, compared to $239.8 million in the same period of the prior year, an increase of 16%. Total revenues for the first nine months of 2007 were $304.1 million, compared to $263.7 million in the same period of the prior year, an increase of 15%. Net income for the first nine months of 2007 was $65.7 million ($1.21 per diluted share), compared to $42.4 million ($0.80 per diluted share) in the same period of the prior year, an increase of 55%. Net income for the first nine months of 2007 included an $8.7 million tax

benefit associated with an April 2007 tax settlement with the Internal Revenue Service, or IRS.

Table of Contents

Corporate Collaborations

In July 2007, we authorized Stratec Biomedical Systems AG, or Stratec, to commence their Phase 2 development activities pursuant to our Development Agreement for the Panther Instrument System. The Development Agreement provides for the development of a fully automated, mid-volume molecular diagnostic instrument by Stratec. Stratec is providing services for the design and development of the Panther Instrument System at a fixed price of $9.4 million, to be paid in installments due upon achievement of specified technical milestones. In addition, we will purchase prototype, validation, pre-production and production instruments, at specified fixed transfer prices, that will cost approximately $10.2 million in the aggregate if we elect to purchase the number of each instrument type we currently expect to purchase. We will also purchase production tooling from Stratec at a cost of approximately $1.2 million.

In May 2007, we announced that Millipore Corporation, or Millipore, will market our Mycoplasma Tissue Culture Non-Isotopic, or MTC-NI, test to its biopharmaceutical customers. This new agreement expands on our existing collaboration with Millipore to create a new generation of nucleic acid tests for the biopharmaceutical market. We developed the MTC-NI test prior to our collaboration with Millipore and it is commercially available today.

In April 2007, we entered into an exclusive collaboration agreement with 3M Company, or 3M, to develop and commercialize rapid nucleic acid tests to detect certain dangerous healthcare-associated infections, such as methicillin-resistant *Staphylococcus aureus*. Under the terms of the agreement, we will be responsible for assay development, which 3M will help fund. 3M will be responsible for integrating these assays onto one of its proprietary integrated instrument platforms currently under development. We will conduct bulk manufacturing of assays, while 3M will produce disposables for use on its instrument. 3M will manage clinical trials and regulatory affairs, and will handle global sales and marketing with co-promotion assistance from our sales representatives. 3M has agreed to pay milestones to us based on technical and commercial progress, and we will share profits from the sale of commercial products.

Product Development

In May 2007, the Food and Drug Administration, or FDA, approved our Procleix TIGRIS system for use with our Procleix Ultrio assay, to screen donated blood, plasma, organs and tissues for HIV-1 and HCV in individual blood donations or in pools of up to 16 blood samples. The system and assay also detect HBV in blood donations that are HBV-positive based on serology tests for HBV surface antigen and core antibodies. The system has not been approved at this time to screen donated blood for HBV, as the initial clinical studies were not designed to, and did not, demonstrate HBV yield . Yield is defined as HBV-infected blood donations that were intercepted by the Procleix Ultrio assay, but that were initially negative based on the serology tests. We and Novartis have initiated a post-marketing study to demonstrate HBV yield and gain the associated donor screening claim. We believe the first of two required yield cases has been identified in the study, although this must be confirmed through a regulatory submission to the FDA.

In March 2007, the FDA approved our Procleix TIGRIS system, to screen donated blood, organs and tissues for WNV using the Procleix WNV assay. The fully automated, high throughput Procleix TIGRIS system can process 1,000 blood samples in about 14 hours. This level of productivity facilitates individual donor testing, which increases screening sensitivity and blood safety. Blood testing sites typically screen for WNV using pooled samples; however, when predetermined WNV prevalence triggers are met in their geographic areas, they switch to individual donor testing.

In January 2007, the United States Army Medical Research and Material Command, which actively manages research programs for the Department of Defense, granted us a $2.5 million award for the development of improved cancer diagnostic assays. In September 2007, this award was increased by $1.1 million to $3.6 million.

Table of Contents

Revenues

We derive revenues from three primary sources: product sales, collaborative research revenue and royalty and license revenue. The majority of our revenues come from product sales, which consist primarily of sales of our NAT assays tested on 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 agreement 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 revenue reflects fees paid to us by Bayer Corporation, or Bayer (now Siemens Medical Solutions Diagnostics, Inc.), and other third parties for the use of our proprietary technology. For the first nine months of 2007, product sales, collaborative research revenue, and royalty and license revenue equaled 91%, 4% and 5%, respectively, of our total revenues of $304.1 million. For the same period in the prior year, product sales, collaborative research revenue, and royalty and license revenue equaled 91%, 6%, and 3%, respectively, of our total revenues of $263.7 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, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. The principal customers for our clinical diagnostics products include large reference laboratories, public health institutions and hospitals.

We supply NAT assays for use in screening blood donations intended for transfusion. Our primary blood screening product in the United States detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments are marketed worldwide 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 third parties, less freight, duty and certain other adjustments specified in our collaboration 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 collaboration agreement with Novartis. With respect to commercial sales of blood screening assays under our collaboration agreement with Novartis that do not include a test for HCV, such as the WNV assay, we receive 50% of net revenues after deduction of appropriate expenses. Our costs related to these products after commercialization primarily include manufacturing costs.

Collaborative research revenue

Under our collaboration 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.

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. In December 2005, the FDA granted marketing approval for our WNV assay on our enhanced semi-automated instrument system, or eSAS, to screen donated human blood. In the first quarter of 2006, upon shipment of FDA-approved and labeled product, we changed the recognition of prospective sales of the WNV assay for use on eSAS from collaborative research revenue to product sales.

The costs associated with collaborative research revenue are based on fully burdened full time equivalent 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 collaborations and, therefore, are not able to quantify all of the direct costs associated with collaborative research revenue.

Table of Contents

Royalty and license revenue

We recognize revenue for royalties due to us upon the manufacture, sale or use of our products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the applicable licensee. Non-refundable license fees are recognized over the related performance period or at the time that we have satisfied all performance obligations.

Cost of product sales

Cost of product sales includes direct material, direct labor, and manufacturing overhead associated with the production of inventories. 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 materials, development lots, and clinical trial lots of product prior to receiving FDA approval for commercial sale. The majority of costs associated with development lots are classified as research and development, or R&D, 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 R&D activities as new product offerings are developed for commercialization. As a result, certain operating costs of our blood screening manufacturing 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 R&D expense prior to FDA approval.

A portion of our blood screening revenues is from sales of TIGRIS instruments to Novartis, which totaled $6.2 million and $6.6 million during the first nine months of 2007 and 2006, respectively. Under our collaboration agreement 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.

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 covering the licensed technology.

R&D expenses include the costs of 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 development lots and clinical trial lots for our blood screening products, further development of our TIGRIS instrument, initial development of a fully automated system for low and mid-volume laboratories, as well as for the development of assays for PCA3, HPV, hospital-acquired infections and for industrial applications.

Table of Contents

Critical accounting policies and estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States 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 inventories, long-lived assets, including license and manufacturing access fees, patent costs and capitalized software, income tax and valuation of stock-based compensation. 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 first nine months of 2007 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, 2006, except for the item discussed below.

New accounting requirement

Effective January 1, 2007, we adopted Financial Accounting Standards Board, or FASB, Interpretation No. 48 Accounting for Uncertainty in Income Taxes an interpretation of Statement of Financial Accounting Standards, or SFAS, No. 109 , or FIN No. 48, 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 No. 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. In accordance with the transition guidance provided by FIN No. 48, we made an adjustment of $1.0 million for the net impact of the change in guidance. The adjustment was accounted for as a reduction in the beginning balance of retained earnings and an increase in the beginning balance of net tax liabilities. We do not anticipate that the adoption of FIN No. 48 will have a material effect on our statements of income and effective tax rate in future periods.

Results of Operations

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2007	2006	$ Change	% Change	2007	2006	$ Change	% Change
	(In millions, except per share data)							
Statement of income:								
Revenues:								
Product sales	$ 97.4	$ 83.5	$ 13.9	17%	$ 278.5	$ 239.8	$ 38.7	16%
Collaborative research revenue	3.1	1.5	1.6	107%	11.2	14.7	(3.5)	(24)%
Royalty and license revenue	1.2	7.3	(6.1)	(84)%	14.4	9.2	5.2	57%
Total revenues	101.7	92.3	9.4	10%	304.1	263.7	40.4	15%
Operating expenses:								
Cost of product sales	31.8	24.3	7.5	31%	91.2	76.2	15.0	20%
Research and development	27.6	24.2	3.4	14%	72.8	63.8	9.0	14%
Marketing and sales	9.6	9.5	0.1	1%	28.6	27.6	1.0	4%
General and administrative	11.4	12.8	(1.4)	(11)%	34.7	34.1	0.6	2%
Total operating expenses	80.4	70.8	9.6	14%	227.3	201.7	25.6	13%

Income from operations	21.3	21.5	(0.2)	(1)%	76.8	62.0	14.8	24%
Total other income, net	3.3	1.9	1.4	74%	8.6	5.1	3.5	69%
Income tax expense	7.4	8.6	(1.2)	(14)%	19.7	24.7	(5.0)	(20)%
Net income	$ 17.2	$ 14.8	$ 2.4	16%	$ 65.7	$ 42.4	$ 23.3	55%
Net income per share								
Basic	$ 0.32	$ 0.29	$ 0.03	10%	$ 1.25	$ 0.82	$ 0.43	52%
Diluted	$ 0.31	$ 0.28	$ 0.03	11%	$ 1.21	$ 0.80	$ 0.41	51%
Weighted average shares outstanding								
Basic	53.2	51.6			52.7	51.4		
Diluted	54.9	53.2			54.2	53.0		

Amounts and percentages in this table and throughout our discussion and analysis of financial conditions and results of operations may reflect rounding adjustments. Percentages have been rounded to the nearest whole percentage.

Table of Contents

Product sales

Product sales increased 17% to $97.4 million in the third quarter of 2007 and 16% to $278.5 million in the first nine months of 2007, from the comparable periods of 2006. The $13.9 million increase in the third quarter of 2007 compared to 2006 was primarily attributed to $7.7 million in higher APTIMA assay sales, $4.8 million in higher blood screening assay sales and $3.3 in higher instrument sales. These increases were partially offset by a $2.8 million decrease in PACE product sales. Blood screening related sales, including assay, instrument, and ancillary sales, represented $45.6 million, or 47% of product sales, in the third quarter of 2007, compared to $40.2 million, or 48% of product sales in the third quarter of 2006. The increase in blood screening related sales during the third quarter of 2007 compared to 2006 was principally attributed to the approval and commercial launch of our WNV assay and international expansion of Procleix Ultrio (HIV-1/HCV/HBV) assay sales. Diagnostic product sales, including assay, instrument, and ancillary sales, represented $51.8 million, or 53% of product sales, in the third quarter of 2007, compared to $43.3 million, or 52% of product sales in the third quarter of 2006. This increase in sales was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions, and market share gains attributed to the assays clinical performance and the availability of our fully automated TIGRIS instrument. Average pricing related to our primary APTIMA products remained consistent with 2006 levels.

The $38.7 million increase in product sales in the first nine months of 2007 compared to 2006 was primarily attributed to $25.8 million in higher APTIMA assay sales and $18.7 million in higher blood screening assay sales, partially offset by a $8.2 million decrease in PACE product sales. Blood screening related sales, including assay, instrument, and ancillary sales, represented $129.0 million, or 46% of product sales, in the first nine months of 2007, compared to $114.0 million, or 48% of product sales in the first nine months of 2006. The increase in blood screening related sales during the first nine months of 2007 compared to 2006 was principally attributed to the approval and commercial launch of our WNV assay and international expansion of Procleix Ultrio (HIV-1/HCV/HBV) assay sales, offset by decreased instrument sales to Novartis. Our share of blood screening revenues is based upon sales of assays by Novartis, blood donation levels and the related price per donation. In 2007, growth of United States blood donation volumes screened using the Procleix HIV-1/HCV assay was relatively flat, as was the related pricing. Diagnostic product sales, including assay, instrument, and ancillary sales, represented $149.5 million, or 54% of product sales, in the first nine months of 2007, compared to $125.8 million, or 52% of product sales in the first nine months of 2006. The increase in 2007 was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions, and market share gains attributed to the assays clinical performance and the availability of our fully automated TIGRIS instrument. Average pricing related to our primary APTIMA products remained consistent with 2006 levels.

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, and continuing pricing pressure. We also expect continuing fluctuations in our manufacture and shipment of blood screening products to Novartis, which vary each period based on Novartis inventory levels and supply chain needs.

Collaborative research revenue

Collaborative research revenue increased 107% in the third quarter of 2007 and decreased 24% in the first nine months of 2007 from the comparable periods of 2006. The $1.6 million increase in the third quarter of 2007 compared to 2006 was primarily the result of a $0.8 million increase in revenue from the U.S. Army Medical Research and Material Command for the development of improved cancer diagnostic assays, and a $0.8 million increase in blood screening development expenses billed to Novartis related to Procleix Ultrio assay development charges.

The $3.5 million decrease in collaborative research revenue in the first nine months of 2007 compared to 2006 was primarily the result of a $9.2 million decrease in revenue from Novartis related to deliveries of WNV tests on a cost recovery basis in the first nine months of 2006, which are now recorded as product sales, and a $1.3 million decrease in reimbursements from Millipore, as the first assay under our collaboration is moving out of the development phase and into commercialization. These decreases were partially offset by a $2.8 million increase in revenue from the U.S. Army Medical Research and Material Command for the development of improved cancer diagnostic assays, a $3.5 million increase in blood screening development expenses billed to Novartis related to Procleix Ultrio assay development, and a $1.2 million increase in revenue from 3M related to our food testing program.

Collaborative research revenue fluctuates based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Under the terms of our collaboration agreement with Novartis, a milestone payment of $10.0 million is due to us in the future if we obtain full FDA approval of our Procleix Ultrio assay for blood screening use on our TIGRIS instrument. Also, milestone payments from 3M are due to us in the future upon achievement of technological and commercial milestones under our hospital-acquired infection and food testing collaborations. There is no guarantee we will achieve these milestones and receive the associated payments under these agreements.

Table of Contents

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.

Royalty and license revenue

Royalty and license revenue decreased 84% in the third quarter of 2007 and increased 57% in the first nine months of 2007 from the comparable periods of 2006. The $6.1 million decrease in the third quarter of 2007 was primarily due to license fee revenue in 2006 from Bayer ($5.0 million) and Tosoh ($1.0 million), both of which related to our settlement of litigation with Bayer.

The $5.2 million increase in the first nine months of 2007 compared to 2006 was principally attributed to a second royalty payment received from Bayer as part of our 2006 settlement agreement ($10.3 million), along with higher Chiron blood plasma royalties ($0.7 million), partially offset by license fee revenue in 2006 from Bayer ($5.0 million) and Tosoh ($1.0 million).

Royalty and license revenue may fluctuate based on the nature of the related agreements and the timing of receipt of license fees. For example, during the first nine months of 2007, our royalty and license revenue increased substantially, primarily as a result of a royalty payment which became due and was received in January 2007 from Bayer as part of our 2006 settlement agreement. 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 31% in the third quarter and 20% in the first nine months of 2007 from the comparable periods of 2006. The $7.5 million increase in the third quarter of 2007 compared to 2006 was principally attributed to higher instrument shipments ($3.4 million), higher APTIMA shipments ($1.2 million), changes in production volumes ($2.4 million), and higher instrument amortization costs ($0.5 million).

The $15.0 million increase in the first nine months of 2007 compared to 2006 was principally attributed to higher blood screening shipments of Procleix Ultrio ($4.0 million) and WNV ($2.7 million) assays, higher APTIMA shipments ($4.3 million), increased amortization of stock-based compensation expense ($1.1 million) and higher instrument amortization ($1.4 million).

Our gross profit margin as a percentage of product sales decreased to 67.3% in both the third quarter and first nine months of 2007, from 70.9% and 68.2%, respectively, in the comparable periods of 2006. The decrease in gross profit margin percentage in 2007 was principally attributed to increased sales of low gross profit margin instruments, increased instrument amortization, increased amortization of stock-based compensation expense, and changes in production volumes. These decreases were partially offset by increases in revenue associated with commercial sales of the WNV assay, and an increase in revenue associated with increased sales of APTIMA.

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.

Table of Contents

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 will be required to deliver the sample results. We have already observed this trend with respect to certain sales in Europe. We are not able to accurately predict the ultimate timing and extent to which our gross margin percentage will be negatively affected as a result of smaller pool sizes or individual donor testing, as this depends on associated price changes. 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.

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 trials. R&D expenses increased 14% in both the third quarter and first nine months of 2007 from the comparable periods of 2006. The $3.4 million increase in the third quarter of 2007 compared to 2006 was primarily due to an increase in spending for development lot activity ($2.7 million) and higher expenses associated with our new building ($0.8 million).

The $9.0 million increase in the first nine months of 2007 compared to 2006 was primarily due to increased spending for development lot activity ($4.3 million), an increase in expenses associated with our new building ($4.3 million), higher salaries and personnel-related expenses ($1.8 million) and an increase in professional fees due to funding commitments for our low to mid-volume instrument ($1.2 million), partially offset by a decrease in stock-based compensation expense due to increased forfeitures ($2.5 million).

Marketing and sales

Our marketing and sales expenses include salaries and other personnel-related expenses, promotional expenses, and outside services. Marketing and sales expenses increased 1% in the third quarter and 4% in the first nine months of 2007 from the comparable periods of 2006.

General and administrative

Our general and administrative, or G&A, expenses include salaries and other personnel-related expenses for finance, legal, strategic planning and business development, public relations and human resources, as well as professional fees for legal, patents and auditing services. G&A expenses decreased 11% in the third quarter and increased 2% in the first nine months of 2007 from the comparable periods of 2006. The $1.4 million decrease in the third quarter of 2007 compared to 2006 was primarily the result of decreased professional fees associated with our two patent infringement lawsuits against Bayer, which we settled in 2006.

Total other income, net

Total other income, net, generally consists of investment and interest income. The $1.4 million net increase in the third quarter of 2007 and the $3.5 million net increase in the first nine months of 2007 from the comparable periods of 2006 were primarily due to an increase in interest income resulting from higher average balances of our short-term investments and higher yields on our investment portfolio.

Income tax expense

Income tax expense decreased to $7.4 million, or 30.0% of pretax income, in the third quarter of 2007, from $8.6 million, or 36.7% of pretax income, in the third quarter of 2006. In the first nine months of 2007, income tax expense decreased to $19.7 million, or 23.0% of pretax income, from $24.7 million, or 36.9% of pretax income, in the first nine months of 2006. The decrease in our effective tax rate in the third quarter was largely the result of higher tax-exempt interest and a favorable adjustment upon completion of our 2006 federal tax return. The decrease in our effective tax rate in the first nine months of 2007 was principally attributed to completion of a U.S. federal audit of our tax returns through 2004, which resulted in an $8.7 million tax benefit associated with a second quarter 2007 tax settlement with the IRS, higher tax-exempt interest and a favorable adjustment upon completion of our 2006 federal tax return.

Table of Contents

Liquidity and capital resources

(In thousands)

	September 30, 2007	December 31, 2006
Cash, cash equivalents and short-term investments	$ 395,073	$ 289,913
Working capital	$ 484,918	$ 342,062
Current ratio	11:1	8:1

Aside from $71.2 million of cash provided by operating activities, the changes in working capital and current ratio from December 31, 2006 to September 30, 2007 were principally attributed to a $10.9 million reduction in tax reserves related to settlement of an IRS audit and reclassification of $4.0 million in income tax payable from current to non-current resulting from the adoption of FIN No. 48 as of January 1, 2007.

(In thousands)

	Nine Months Ended September 30,		
	2007	2006	$ Change
Cash provided by (used in):			
Operating activities	$ 71,181	$ 72,041	$ (860)
Investing activities	(145,193)	(70,109)	75,084
Financing activities	52,712	27,321	25,391
Purchases of property, plant and equipment (included in investing activities above)	$ (17,674)	$ (40,126)	$ (22,452)

Historically, we have financed our operations through cash from operations, including cash received from collaborative research agreements, royalty and license fees, and cash from capital contributions. At September 30, 2007, we had $395.1 million of cash and cash equivalents and short-term investments.

The $0.9 million decrease in net cash provided by operating activities during the first nine months of 2007 compared to the same period of the prior year was primarily due to a decrease in income tax payable ($16.6 million), related to the favorable settlement of the IRS federal tax audit, and an increase in accounts receivable ($23.4 million) due to overall increased sales, specifically increased instrument sales. These decreases were mostly offset by higher net income ($23.4 million), higher depreciation and amortization expense ($5.8 million), and a net decrease in inventories ($8.0 million).

The $75.1 million increase in net cash used in investing activities during the first nine months of 2007 compared to the same period of the prior year included an increase in purchases (net of sales) of short-term investments ($104.5 million), partially offset by a decrease in capital expenditures ($22.5 million) and investments ($7.0 million). The increase in purchases of short-term investments was driven by the reinvestment of excess cash generated by operating activities, as well as proceeds from the exercise of stock options. The decline in capital expenditures was primarily due to the completion of construction of our new building in 2006.

The $25.4 million increase in net cash provided by financing activities during the first nine months of 2007 compared to the same period of the prior year was principally attributed to an increase in proceeds from the exercise of stock options ($21.6 million) and an increase in the associated excess tax benefits ($4.8 million). 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 Employee Stock Purchase Plan, or 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.

Table of Contents

In May 2006, we completed construction of an additional building on our main San Diego campus. This new building consists of an approximately 292,000 square foot shell and currently has 214,000 square feet built-out with interior improvements. Approximately 78,000 square feet of unimproved expansion space remains to accommodate future growth. Construction costs as of September 30, 2007 were approximately $46.3 million. These costs were capitalized as incurred and depreciation commenced upon our move-in during May 2006. In November 2004, the FASB issued SFAS No. 151, Inventory Costs an Amendment of Accounting Research Bulletin No. 43, Chapter 4, or SFAS No. 151, clarifying the accounting for idle facility expense to be recognized as a current-period charge. Costs associated with our San Diego campus are generally allocated based on square feet. Costs that are allocated to expansion space are expensed in the period incurred in accordance with SFAS No. 151.

We implemented a new enterprise resource planning, or ERP, system that cost approximately $4.9 million in 2004. We incurred $1.7 million in additional costs in the first nine months of 2007, and $3.3 million and $2.9 million in costs during fiscal years 2006 and 2005, respectively. We expect to incur up to $2.2 million in costs in the aggregate in 2007 for 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, 2007 were as follows (in thousands):

	Total	2007	2008	2009	2010	Thereafter
Operating leases [1]	$ 454	$ 217	$ 167	$ 70	$	$
Material purchase commitments [2]	34,244	6,254	19,739	5,438	813	2,000
Collaborative commitments [3]	13,259	443	10,766	1,400	650	
Total [4]	$ 47,957	$ 6,914	$ 30,672	$ 6,908	$ 1,463	$ 2,000

(1) Reflects obligations on facilities under operating leases in place as of September 30, 2007. Future minimum lease payments are included in the table above.

(2) Amounts represent our minimum purchase commitments from key vendors for the TIGRIS and Panther instruments, as well as raw materials used

in manufacturing. Of the $21.4 million expected to be used to purchase TIGRIS instruments, we anticipate that approximately $15.4 million of these instruments will be sold to Novartis. For the Panther instrument, these amounts include $11.5 million expected to be used to purchase prototype, validation, pre-production and production instruments pursuant to the Stratec Development Agreement and potential minimum purchase commitments under our Supply Agreement. Our obligations under the Supply Agreement are contingent on successful completion of all activities under the Development Agreement.

(3)

In addition to the minimum payments due under our collaborative agreements included in the table above, we may be required to pay up to $11.1 million in milestone payments, plus royalties on net sales of any products using specified technology. We may also be required to pay up to $7.5 million in future development costs in the form of milestone payments.

(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 liabilities for deferred employee compensation which totaled $3.2 million at September 30, 2007. The payments related to the deferred compensation are not included in the table above because they are typically dependent upon when certain key employees retire or otherwise terminate their employment. At this time, we cannot reasonably predict when these events may occur.

Our primary short-term needs for capital, which are subject to change, include continued R&D of new products, costs related to commercialization of products and purchases of TIGRIS instruments for placement with our customers. Certain R&D costs may be funded under collaboration agreements with partners.

Table of Contents

We believe that our available cash balances, anticipated cash flows from operations and proceeds from stock option exercises 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 Securities and Exchange Commission, or SEC, relating to the possible future sale of up to an aggregate of $150 million of debt or equity securities. To date, we have not raised any funds under this registration statement.

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

We do not currently have and have never had any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Available Information

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities. A 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately $6.0 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. 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, 2007 were not material. Under our collaboration agreement with Novartis, a growing portion of blood screening product sales is from western European countries. As a result, our international blood screening product sales are affected by changes in the foreign currency exchange rates of those countries where Novartis business is conducted in Euros or other local currencies. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. Based on international blood screening product sales during the first nine months of 2007, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.3 million

annually. We believe that our business operations are not exposed to market risk relating to commodity prices.

Table of Contents

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, 2007.

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, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 10 Litigation, of the Notes to Consolidated Financial Statements included in Item 1 of Part I of this report and is incorporated by reference herein. 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, 2006.

Table of Contents

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 costs we incur in connection with manufacturing developmental lots and clinical trial lots. 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 cycles accurately. In addition, we base our internal projections of our blood screening product sales and international sales of various diagnostic products on projections prepared by our distributors of these products and therefore we are dependent upon the accuracy of those projections. We expect continuing fluctuations in our manufacture and shipment of blood screening products to Novartis, which vary each period based on Novartis inventory levels and supply chain needs. 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. Furthermore, failure to achieve our operational goals may inhibit our targeted growth plans and the successful implementation of our strategic objectives.

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 Siemens to distribute some of our clinical diagnostic products for the detection of viral microorganisms. Commercial product sales by Novartis accounted for 46% of our total revenues for the first nine months of 2007 and 43% of our total revenues for 2006. As of September 30, 2007, we believe our collaboration agreement with Novartis will terminate in 2012 unless extended by the mutually agreed 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. We do not know what effect, if any, Novartis acquisition of Chiron, our original corporate partner, 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 Siemens, as assignee of Bayer, for the distribution of certain 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 be terminated, as we requested, except as to the qualitative HCV assays and as to quantitative ASRs for HCV. Siemens 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 Siemens. The arbitrator s March 3, 2006 supplemental award determined that we are not obligated to pay 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.

Table of Contents

On December 31, 2006, Bayer completed the sale of its diagnostics division to Siemens. 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 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 collaboration 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 successfully market 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 funding development and for 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, we believe our collaboration agreement with Novartis will terminate in 2012 unless extended by the mutually agreed 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.

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 Siemens, 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 have initiated an in-service reliability improvement program for our TIGRIS instrument. However, this program may not result in the desired improvements in operating reliability of the instrument. Additionally, failure to resolve reliability issues could limit market acceptance of the instrument, adversely affect our reputation, and prevent us from retaining our existing customers or attracting new customers.

Table of Contents

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 and quantify 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. The development of a new instrument platform, if any, in turn may require the modification of existing assays for use with the new instrument, and additional time-consuming and costly 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. We have experienced delays in receiving FDA clearance in the past. Regulatory clearance or approval of any new products we may develop 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. Failure to timely achieve regulatory approval for our products and introduce products to market could negatively impact our growth objectives and financial performance.

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, public health and hospital laboratories. 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, Abbott, Becton Dickinson, Siemens and bioMérieux, currently 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. Our existing competitors or new market entrants may be in better position than we are 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. 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 we do. 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, any of which may adversely impact our customer retention and market share.

Competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue or market acceptance. Some of our competitors have developed real time or kinetic nucleic acid assays and semi-automated instrument systems for those assays. Additionally, some of our competitors are developing assays that permit the quantitative detection of multiple analytes (or quantitative multiplexing). Although we are evaluating and/or developing such technologies, we believe some of our competitors are 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 and Siemens with respect to immunoassay products. In the future, our blood screening products also may compete with viral inactivation or reduction technologies and blood substitutes.

Table of Contents

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 using NAT. 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 (now Siemens), together with the right to grant certain additional HIV and HCV sublicenses in the field to third parties. Bayer s rights have now been assigned to Siemens as part of Bayer s December 2006 sale of its diagnostics business. 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 Siemens 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.

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.

We recently entered into collaboration agreements to develop NAT products for detecting microorganisms in selected water applications, and for microbiological and virus monitoring in the biotechnology, pharmaceutical and food 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 and there is no guarantee that new products will be successfully developed. We will need to design and execute specific product development plans in conjunction with our collaborative partners and 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 costly than existing methods. We will be reliant on our collaborators 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, we may not be able to successfully develop commercially viable products for application in industrial testing or any other new markets.

Failure to manufacture our products in accordance with product specifications could result in increased costs, lost revenues, customer dissatisfaction or voluntary product recalls, any of which could harm our profitability and commercial reputation.*

Properly manufacturing our complex nucleic acid products requires precise technological execution and strict compliance with regulatory requirements. We may experience problems in the manufacturing process for a number of reasons, such as equipment malfunction or failure to follow specific protocols. If problems arise during the production of a particular product lot, that product lot may need to be discarded or destroyed. This could, among other things, result in increased costs, lost revenues and customer dissatisfaction. If problems are not discovered before the product lot is released to the market, recall and product liability costs may also be incurred. In the past, we have voluntarily recalled certain product lots for failure to meet product specifications. Any failure to manufacture our products in accordance with product specifications could have a material adverse effect on our revenues, profitability and commercial reputation.

Table of Contents

Disruptions in the supply of raw materials and consumable goods or issues associated with the quality thereof 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 or not at all. 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 products and limit our growth.

Our current supplier of certain key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is Roche Molecular Biochemicals. We have a supply and purchase agreement for DNA oligonucleotides for human papillomavirus with Roche Molecular Systems. Each of these entities is an affiliate of Roche Diagnostics GmbH, one of our primary competitors. We currently are involved in proceedings with Digene regarding the supply and purchase agreement with Roche Molecular Systems. Digene has filed a demand for binding arbitration against Roche that challenges the validity of the supply and purchase agreement. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and seeks a determination that the supply and purchase agreement is null and void. There can be no assurance that these matters will be resolved in our favor.

We have only one third-party manufacturer for each of our instrument product lines, which exposes us to increased risks associated with production delays, 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 production delays, 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 instrument 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 manufacture of our instruments. Because we place orders with our manufacturers based on forecasts of expected demand for our instruments, 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.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, these regulations.*

The clinical diagnostic and blood screening products we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. 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.

Table of Contents

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. 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 certification with the International Organization for Standardization, 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.

The use of our diagnostic products is also affected by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some clinical laboratories from using some or all of our diagnostic products.

Certain of the industrial testing products that we intend to develop may be subject to government regulation, and market acceptance may be subject to the receipt of certification from independent agencies. We will be reliant on our industrial collaborators in these markets to obtain any necessary approvals. There can be no assurance that these approvals will be received.

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 and delays in launching products, which would harm our operating results.

Our gross profit margin percentage on the sale of blood screening assays will decrease upon the implementation of smaller pool size testing and 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. Since Novartis sells our blood screening assays to blood collection centers on a per donation basis, our profit margins are greater when a single test can be used to screen multiple donor samples.

The blood screening market is transitioning from pooled testing of large numbers of donor samples to smaller pool sizes and, we expect, will ultimately move to individual donor testing. A greater number of tests will be required for smaller pool sizes and individual donor testing than are now required. Under our collaboration agreement with Novartis, we bear the cost of manufacturing our blood screening assays. The greater number of tests required for smaller pool sizes and 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 blood screening assays will decrease upon the adoption of smaller pool sizes and individual donor testing. We have already observed this trend with respect to certain sales in Europe. We are not able to predict accurately the ultimate extent to which our gross profit margin percentage will be negatively affected as a result of smaller pool sizes and individual donor testing, because we do not know the ultimate selling price that Novartis would charge to the end user.

Table of Contents

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 2007 and 48% of our total revenues for 2006. 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 and Laboratory Corporation of America were our only customers that accounted for greater than 10% of our total revenues for the first nine months of 2007. We also received a one-time royalty payment of $10.3 million from Bayer in the first quarter of 2007 pursuant to our settlement agreement. In addition, various state and city public health agencies accounted for an aggregate of 10% of our total revenues in the first nine months of 2007, as well as 9% of our total revenues in fiscal year 2006. 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 volume or pricing 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 440 United States and foreign patents covering our products and technologies as of September 30, 2007, 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 February 6, 2024 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.

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.

Table of Contents

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. Our patent disputes with Bayer were resolved by settlement agreement in August 2006. In December 2006, Digene Corporation filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution of the American Arbitration Association in New York. Digene s demand asserts, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and seeks a determination that the supply and purchase agreement is null and void. On July 13, 2007, the ICDR arbitrators granted our petition to join the arbitration. On August 27, 2007, Digene filed an amended arbitration demand and asserted a claim against us for tortious interference with the cross-license agreement. The arbitration hearing in this matter has been set for October 2008.

On December 8, 2006, we filed a complaint in the Superior Court of the State of California for the County of San Diego naming Digene as defendant and the Roche entities as nominal defendants. The complaint sought a declaratory judgment that the supply and purchase agreement was valid and did not constitute a license or sublicense of the patents covered by the cross-license agreement between Roche and Digene. On July 26, 2007, following the ICDR arbitrators decision to permit the Company to join the arbitration, the San Diego County Superior Court entered judgment dismissing the Company s complaint.

We hold certain rights in the blood screening and clinical diagnostics fields under patents originally 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), originally issued to Chiron (now Novartis). The first interference was 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 second interference was 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)). We are informed that the Patent and Trademark Office determined that Institut Pasteur was the first to invent the subject matter at issue and that Novartis has filed an action in the United States District Court for the District of Columbia challenging the decision of the Patent and Trademark Office. If Novartis does not prevail in the proceedings, Institut Pasteur may obtain patent rights covering the detection of HIV and those patent rights may cover our HIV tests. There can be no assurances as to the ultimate outcome of this matter.

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.

Table of Contents

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, 2007, we had approximately $225.4 million of long-lived assets, including $16.6 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 $49.5 million of capitalized license and manufacturing access fees, patents and purchased intangibles. Additionally, we had $62.3 million of land and buildings, $16.3 million of tenant improvements, $0.5 million of construction in-progress and $52.1 million of equipment and furniture and fixtures. The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable.

These events or changes might include a significant decline in market share, a significant decline in profits, rapid changes in technology, significant litigation, an inability to successfully deliver an instrument to the marketplace and attain customer acceptance 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.

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. Our effective tax rate can also be impacted by changes in estimates of prior years items, past and future levels of research and development spending, the outcome of audits by federal, state and foreign jurisdictions and changes in overall levels of income before tax.

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 sufficient revenues to maintain profitability in the future. Our failure to maintain profitability in the future could cause the market price of our common stock to decline.

Table of Contents

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 affect 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.

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, 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 or quantify 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, clinical and validation testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates.

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 products 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.

Table of Contents

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 a problem and correct it. Our products may be subject to additional recalls in the future. Although none of our past product recalls 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 21% of our total revenues for the first nine months of 2007 and 22% of our total revenues for 2006. Sales by Novartis of our blood screening products outside of the United States accounted for 76% of our international revenues for the first nine months of 2007 and 77% of our international revenues for 2006. 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 4% of our international sales in the first nine months of 2007 and 5% of our international sales for the year ended December 31, 2006.

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 and parvo B19, as well as HBV, HIV-1 and HCV. When we seek to enter a new international market, we may 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. We have already observed this trend with respect to certain sales in Europe. 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 institutions 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 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.

Table of Contents

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 reference laboratories, public health institutions 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, these entities 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.

We are dependent on technologies we license, and if we fail to maintain our licenses or 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. 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. Many of these licenses provide us with exclusive rights to the subject technology or disease marker. If our license with respect to any of these technologies or markers is terminated for any reason, we may not be able to sell products that incorporate the technology. In addition, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license.

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 the 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.

Our products and manufacturing processes require access to technologies and materials that may be subject to patents or other intellectual property rights held by third parties. We may discover that we need to obtain additional intellectual property rights in order to commercialize our products. We may be unable to obtain such rights on commercially reasonable terms or at all, which could adversely affect our ability to grow our business.

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 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. The position of Vice President, Research and Development has been vacant since April 2007 and the position of Vice President, Operations has been vacant since September 2007.

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 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.

Table of Contents

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 could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license or strategic alliance.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would result in dilution to our stockholders. If the price of our equity is low or volatile, we may not be able to use our common stock as consideration to acquire other companies. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us.

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 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, and provisions of Delaware law 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.

Table of Contents

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 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.

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 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 and this 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.

39

Table of Contents

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 revenue forecasts are based in large part on data and estimates we receive from our partners and distributors. 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 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 Global Select 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, in all reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

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

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
July 1-31, 2007		$		$
August 1-31, 2007	16,742	60.95		
September 1-30, 2007				
Total	16,742[(1)]	$ 60.95		$

(1) During the third quarter of 2007, we repurchased and retired 16,742 shares of our common stock, at an average per share price of

			$60.95, withheld by us to satisfy employee tax obligations upon vesting of restricted stock granted under our 2003 Incentive Award Plan. We may make similar repurchases in the future to satisfy employee tax obligations upon vesting of restricted stock and Deferred Issuance Restricted Stock. As of September 30, 2007, we had an aggregate of 259,980 shares of restricted stock and 80,000 shares of Deferred Issuance Restricted Stock Awards outstanding.

Table of Contents

Item 6. Exhibits

Exhibit Number		Description
2.1(1)		Separation and Distribution Agreement, dated and effective as of May 24, 2002, and amended and restated as of August 6, 2002, by and between Chugai Pharmaceutical Co., Ltd. and Gen-Probe Incorporated.
3.1(1)		Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(2)		Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(3)		Form of Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(4)		Certificate of Elimination of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)		Specimen common stock certificate.
10.100	*	Development Agreement for Panther Instrument System, effective November 22, 2006, by and between the Company and STRATEC Biomedical Systems AG.
10. 101	*	Supply Agreement for Panther Instrument System, effective November 22, 2006, by and between the Company and STRATEC Biomedical Systems AG.
10. 102	*	Letter Agreement regarding Development Agreement for Panther Instrument System, dated July 17, 2007, by and between the Company and STRATEC Biomedical Systems AG.
31.1		Certification dated November 5, 2007, of Principal Executive Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2		Certification dated November 5, 2007, of Principal Financial Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1		Certification dated November 5, 2007, of Principal Executive Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2		Certification dated November 5, 2007, of Principal Financial Officer required pursuant to 18 U.S.C. 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 Quarterly Report on Form 10-Q filed with the SEC on August 9, 2004.

(3) Incorporated by reference to Gen-Probe s Report on Form 8-K filed with the SEC on February 14, 2007.

(4) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K for the year ended December 31, 2006 filed with the SEC on February 23, 2007.

Table of Contents

SIGNATURES

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

GEN-PROBE INCORPORATED

DATE: November 5, 2007

By: /s/ Henry L. Nordhoff
Henry L. Nordhoff
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

DATE: November 5, 2007

By: /s/ Herm Rosenman
Herm Rosenman
Senior Vice President Finance and Chief Financial
Officer (Principal Financial Officer and Principal Accounting Officer)