GEN PROBE INC
Form 10-Q
October 31, 2008

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

(Mark One)

þ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended September 30, 2008

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	
(Address of Principal Executive Offices)	**92121** (Zip Code)

(858) 410-8000

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company 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 30, 2008, there were 54,375,288 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

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

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,366	$ 75,963
Short-term investments	481,127	357,531
Trade accounts receivable, net of allowance for doubtful accounts of $700 and $719 at September 30, 2008 and December 31, 2007, respectively	28,632	32,678
Accounts receivable other	3,684	11,044
Inventories	53,241	48,540
Deferred income tax short term	9,985	8,825
Prepaid income tax	2,358	2,390
Prepaid expenses	10,409	17,505
Other current assets	7,068	4,402
Total current assets	670,870	558,878
Property, plant and equipment, net	139,554	129,493
Capitalized software, net	14,037	15,923
Goodwill	18,621	18,621
Deferred income tax long term	7,744	7,942
License, manufacturing access fees and other assets, net	58,368	58,196
Total assets	$ 909,194	$ 789,053
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 19,163	$ 11,777
Accrued salaries and employee benefits	25,908	20,997
Other accrued expenses	4,081	4,014
Income tax payable	3,909	846
Deferred revenue short term	1,544	2,836
Total current liabilities	54,605	40,470
Non-current income tax payable	4,216	3,958
Deferred income tax long term	69	75
Deferred revenue long term	2,500	4,607
Deferred rent		10
Deferred compensation plan liabilities	2,330	1,893
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding	5	5

Common stock, $0.0001 par value per share; 200,000,000 shares authorized, 54,374,929 and 53,916,298 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively				
Additional paid-in capital		439,402		415,229
Accumulated other comprehensive (loss)/income		(949)		1,604
Retained earnings		407,016		321,202
Total stockholders equity		845,474		738,040
Total liabilities and stockholders equity	$	909,194	$	789,053

See accompanying notes to consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Product sales	$ 108,253	$ 97,402	$ 323,461	$ 278,451
Collaborative research revenue	11,343	3,118	18,453	11,239
Royalty and license revenue	1,581	1,213	21,640	14,375
Total revenues	121,177	101,733	363,554	304,065
Operating expenses:				
Cost of product sales	30,681	31,810	95,827	91,148
Research and development	24,507	27,582	76,941	72,813
Marketing and sales	10,709	9,651	34,070	28,580
General and administrative	12,908	11,380	38,516	34,742
Total operating expenses	78,805	80,423	245,354	227,283
Income from operations	42,372	21,310	118,200	76,782
Interest income	4,167	3,327	12,274	8,935
Interest expense	(1)		(3)	30
Other income/(expense)	(1,929)	6	(647)	(355)
Total other income, net	2,237	3,333	11,624	8,610
Income before income tax	44,609	24,643	129,824	85,392
Income tax expense	15,531	7,392	44,010	19,664
Net income	$ 29,078	$ 17,251	$ 85,814	$ 65,728
Net income per share:				
Basic	$ 0.54	$ 0.32	$ 1.59	$ 1.25
Diluted	$ 0.53	$ 0.31	$ 1.56	$ 1.21
Weighted average shares outstanding:				
Basic	54,084	53,221	53,882	52,661
Diluted	55,322	54,857	55,117	54,210

See accompanying notes to consolidated financial statements.

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

	Nine Months Ended September 30,	
	2008	**2007**
Operating activities		
Net income	$ 85,814	$ 65,728
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	26,217	25,518
Amortization of premiums on investments, net of accretion of discounts	5,118	3,379
Stock-based compensation charges	15,012	14,487
Stock-based compensation income tax benefits	3,025	2,031
Excess tax benefit from stock-based compensation	(2,510)	(13,055)
Gain on sale of stock holdings of Molecular Profiling Institute, Inc.	(1,600)	
Impairment charges	5,086	
Loss on disposal of property and equipment	38	202
Changes in assets and liabilities:		
Accounts receivable	11,403	(15,861)
Inventories	(4,270)	2,660
Prepaid expenses	7,060	(6,538)
Other current assets	(2,255)	(2,756)
Other long term assets	(510)	(930)
Accounts payable	7,381	1,116
Accrued salaries and employee benefits	4,922	6,328
Other accrued expenses	96	5,343
Income tax payable	2,926	(14,544)
Deferred revenue	(3,399)	202
Deferred income tax	(961)	794
Deferred rent	(10)	(88)
Deferred compensation plan liabilities	436	544
Net cash provided by operating activities	159,019	74,560
Investing activities		
Proceeds from sales and maturities of short-term investments	94,103	54,012
Purchases of short-term investments	(225,290)	(182,449)
Purchases of property, plant and equipment	(30,530)	(17,674)
Capitalization of intangible assets, including license and manufacturing access fees	(1,868)	(2,127)
Sale of stock holdings of Molecular Profiling Institute, Inc.	4,100	
Cash paid for Roche manufacturing access fees	(10,000)	
Other items, net	10	(334)
Net cash used in investing activities	(169,475)	(148,572)
Financing activities		
Repurchase and retirement of restricted stock for payment of taxes	(1,309)	(1,020)

Repurchase and retirement of common stock	(9,992)	
Excess tax benefit from stock-based compensation	2,510	13,055
Proceeds from issuance of common stock	17,848	40,677
Net cash provided by financing activities	9,057	52,712
Effect of exchange rate changes on cash and cash equivalents	(198)	283
Net decrease in cash and cash equivalents	(1,597)	(21,017)
Cash and cash equivalents at the beginning of period	75,963	87,905
Cash and cash equivalents at the end of period	$ 74,366	$ 66,888

See accompanying notes to consolidated financial statements.

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Notes to the Consolidated Financial Statements (unaudited)

Note 1 Summary of significant accounting policies

Basis of presentation

The accompanying interim consolidated financial statements of Gen-Probe Incorporated (Gen-Probe or the Company) at September 30, 2008, and for the nine month periods ended September 30, 2008 and 2007, 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, 2008.

Certain prior year amounts have been reclassified to conform with the current year presentation. In the fourth quarter of 2007, the Company began reporting the amortization of premiums on investments, net of accretion of discounts, as an adjustment to reconcile net income to net cash provided by operating activities on the consolidated statements of cash flows. These amounts were previously reported as part of the proceeds from sales and maturities of short-term investments under investing activities. This reclassification increased cash provided by operating activities and decreased net cash used in investing activities for the nine month period ended September 30, 2007 by $3,379,000.

These unaudited consolidated financial statements and footnotes thereto should be read in conjunction with the audited consolidated financial statements and footnotes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2007.

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), Gen-Probe Italia SRL, and Molecular Light Technology Limited (MLT) and MLT s 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 consolidated financial statements. All intercompany transactions and balances have been eliminated in consolidation.

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, recognition of revenues, the valuation of inventories and long-lived assets, including patent costs, capitalized software and 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. The functional currency of Gen-Probe Italia SRL is the Euro. 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 (loss)/income.

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Revenue recognition

The Company records shipments of its clinical diagnostic products as product sales when the product is shipped and title and risk of loss has passed and when collection of the resulting receivable is reasonably assured.

The Company manufactures blood screening products according to demand specifications of its collaboration partner, Novartis. Upon shipment to Novartis, the Company recognizes blood screening product sales at an agreed upon transfer price and records the related cost of products sold. Based on the terms of the Company s collaboration agreement with Novartis, the Company s ultimate share of the net revenue from sales to the end user is not known until reported to the Company by Novartis. The Company then adjusts blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting its ultimate share of net sales by Novartis of these products, less the transfer price revenues previously recognized.

Product sales also include the sales or rental revenue associated with the delivery of the Company s proprietary integrated instrument platforms that perform its diagnostic assays. Generally, the Company provides its instrumentation to clinical laboratories and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, the Company recovers the cost of providing the instrumentation in the amounts it charges for its diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

The Company sells its instruments to Novartis for use in blood screening and records these instrument sales upon delivery since Novartis is responsible for the placement, maintenance and repair of the units with its customers. The Company also sells instruments to its clinical diagnostics customers and records sales of these instruments upon delivery and receipt of customer acceptance. Prior to delivery, each instrument is tested to meet Company and Food and Drug Administration (FDA) specifications, and is shipped fully assembled. Customer acceptance of the Company s instrument systems requires installation and training by the Company s technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating, and testing the instrumentation.

The Company records as collaborative research revenue shipments of its blood screening products in the United States and other countries in which the products have not received regulatory approval. This is done because price restrictions apply to these products prior to FDA marketing approval in the United States and similar approvals in foreign countries. Upon shipment of FDA-approved and labeled products following commercial approval, the Company classifies sales of these products as product sales in its consolidated financial statements.

The Company follows the provisions of Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF Issue No. 00-21), for multiple element revenue arrangements. EITF Issue No. 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the deliverables in a revenue arrangement constitute separate units of accounting according to the EITF Issue No. 00-21 separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue-recognition policy must be determined for the entire arrangement, and all non-refundable upfront license fees are deferred and recognized as revenues on a straight-line basis over the expected term of the Company s continued involvement in the collaborations.

The Company recognizes collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated monthly contracted amounts are earned in relative proportion to the performance required under the contracts. Non-refundable license fees are recognized over the related performance period or at the time that the Company has satisfied all performance obligations. Milestone payments are recognized as revenue upon the achievement of specified milestones when (i) the Company has earned the milestone payment, (ii) the milestone is substantive in nature and the achievement of the milestone is not reasonably assured at the inception of the agreement, (iii) the fees are non-refundable, and (iv) performance obligations after the milestone achievement will continue to be funded by the collaborator at a level comparable to the level before the milestone achievement. Any amounts received

prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheet.

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Royalty revenue is recognized related to the sale or use of the Company s products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and adjusts 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, the Company recognizes 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 the Company has satisfied all performance obligations.

Adoption of recent accounting pronouncements

SFAS No. 157

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors request for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair valued measurements on earnings. SFAS No. 157 applies whenever standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFA No. 157 is effective for financial assets and liabilities in financial statements issued for fiscal years beginning after November 15, 2007.

The Company adopted this statement for financial assets and liabilities measured at fair value effective January 1, 2008. There was no material financial statement impact as a result of adoption. In accordance with the guidance of FASB Staff Position (FSP) No. 157-2, Effective Date of FASB Statement No. 157, the Company has postponed adoption of the standard for non-financial assets and liabilities that are measured at fair value on a non-recurring basis, until the fiscal year beginning after November 15, 2008. The Company does not anticipate adoption will have a material impact on its consolidated financial position, results of operations or liquidity.

In October 2008, the FASB issued FSP No. 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active (FSP No. 157-3). FSP No. 157-3 clarifies the application of SFAS No. 157 in a market that is not active, and is effective as of the issue date, including application to prior periods for which financial statements have not been issued. The Company adopted this statement effective October 10, 2008. There was no material financial statement impact as a result of adoption. See Note 4 for more information.

SFAS No. 159

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred (e.g., debt issue costs). The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007.

The Company adopted this statement effective January 1, 2008. During the first nine months of 2008, the Company did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

EITF No. 07-3

In June 2007, the FASB ratified EITF Issue No. 07-3, Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF Issue No. 07-3). EITF Issue No. 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future

research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF Issue No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007.

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The Company adopted this statement effective January 1, 2008. There was no material financial statement impact as a result of adoption.

Note 2 Stock-based compensation

The following table summarizes the stock-based compensation expense that the Company recorded in its consolidated statements of income for the three and nine month periods ended September 30, 2008 and 2007 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of product sales	$ 591	$ 715	$ 1,778	$ 2,495
Research and development	1,744	1,470	4,445	3,619
Marketing and sales	767	661	2,069	1,712
General and administrative	2,682	2,454	6,720	6,661
Total	$ 5,784	$ 5,300	$ 15,012	$ 14,487

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 employee stock purchase plan (ESPP) for the three and nine month periods ended September 30, 2008 and 2007:

	Stock Option Plans				ESPP			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007	2008	2007	2008	2007
Risk-free interest rate	3.1%	4.7%	3.0%	4.7%	3.3%	5.0%	3.3%	5.0%
Volatility	33%	37%	33%	36%	34%	29%	34%	29%
Dividend yield								
Expected term (years)	4.2	4.2	4.2	4.2	0.5	0.5	0.5	0.5
Resulting average fair value	$ 18.90	$ 22.42	$ 18.64	$ 21.13	$ 12.07	$ 13.82	$ 13.22	$ 12.89

The Company s unrecognized stock-based compensation expense, before income tax and adjusted for estimated forfeitures, related to outstanding unvested share-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, 2008
Options	1.5	$ 41,481
ESPP	0.2	90
Restricted stock	2.1	14,206
Deferred issuance restricted stock	1.7	2,614
		$ 58,391

At September 30, 2008, the Company had 271,073 shares of unvested restricted stock and 80,000 shares of deferred issuance restricted stock from awards that had a weighted average grant date fair value of $56.09 per share. The fair value of the 60,845 shares of restricted stock and deferred issuance restricted stock that vested during the first nine months of fiscal 2008 was approximately $3,298,000.

Note 3 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), Share-Based Payment. 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.

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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,	
	2008	2007	2008	2007
Net income	$ 29,078	$ 17,251	$ 85,814	$ 65,728
Weighted average shares outstanding Basic	54,084	53,221	53,882	52,661
Effect of dilutive securities outstanding	1,238	1,636	1,235	1,549
Weighted average shares outstanding Diluted	55,322	54,857	55,117	54,210
Net income per share:				
Basic	$ 0.54	$ 0.32	$ 1.59	$ 1.25
Diluted	$ 0.53	$ 0.31	$ 1.56	$ 1.21

Dilutive securities include stock options and restricted stock subject to vesting. Potentially dilutive securities totaling 2,127,132 and 1,493,973 shares for the three month periods ended September 30, 2008 and 2007, respectively, and 1,980,907 and 1,507,776 shares for the nine month periods ended September 30, 2008 and 2007, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Note 4 Fair value measurement

The Company adopted SFAS No. 157 effective January 1, 2008 for financial assets and liabilities measured at fair value. SFAS No. 157 defines fair value, expands disclosure requirements around fair value and specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company s market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. A financial instrument s categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the Company s valuation methodologies used for instruments measured at fair value, as well as the general classification of such instruments pursuant to the valuation hierarchy. Where appropriate, the description includes details of the valuation models, the key inputs to those models, as well as any significant assumptions.

Assets and liabilities measured at fair value on a recurring basis:

The Company s available-for-sale securities are comprised of tax advantaged municipal securities and money market funds. When available, the Company generally uses quoted market prices to determine fair value, and classifies such items in Level 1. If quoted market prices are not available, prices are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs,

such as interest rates and yield curves that are observable at commonly quoted intervals. The Company classifies such items in Level 2. For the quarter ended September 30, 2008, based on current market conditions and evolving interpretation of SFAS No. 157, the Company determined that municipal securities previously classified as Level 1, should be classified as Level 2. Because Level 1 inputs are those that have identical securities traded on an active market, and these individual securities have varying maturities and are more comparable to similar securities traded on a market that is not active, the Company determined that a Level 2 classification is more appropriate. The change in classification in no way indicates a decrease in the underlying value of the assets. In addition, money market funds were added to the table with Level 1 or Level 2 classification based on the availability of quoted market prices.

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The following table presents the financial instruments carried at fair value, by caption on the consolidated balance sheets and by SFAS No. 157 valuation hierarchy (as described above) as of September 30, 2008 (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total carrying value in the consolidated balance sheet
Money market funds	$ 6,903	$ 14,705	$	$ 21,608
Short-term investments		481,127		481,127
Total assets at fair value	$ 6,903	$ 495,832	$	$ 502,735

Assets and liabilities measured at fair value on a non-recurring basis:

Certain assets and liabilities are measured at fair value on a non-recurring basis and therefore are not included in the table above. Items valued using such internally generated valuation techniques are classified according to the lowest level input or value driver that is significant to the valuation. Thus, an item may be classified in Level 3 even though there may be some significant inputs that are readily observable. Such instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (for example, when there is evidence of impairment).

Equity investment in private company

In 2006, the Company invested in Qualigen, Inc. (Qualigen), a private company. The valuation of investments in non-public companies requires significant management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such assets. The Company s equity investments in private companies are valued initially based upon the transaction price under the cost method of accounting. Equity investments in non-public companies are classified in Level 3 of the fair value hierarchy. The Company s investment in Qualigen, which totaled approximately $5,403,000 as of September 30, 2008, is included in license, manufacturing access fees and other assets, net on the consolidated balance sheets.

The Company records impairment charges when an investment has experienced a decline that is other-than-temporary. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. Future adverse changes in market conditions or poor operating results of investees could result in losses or an inability to recover the carrying value of the investments, thereby possibly requiring impairment charges in the future. When assessing investments in private companies for an other-than-temporary decline in value, the Company considers such factors as, among other things, the share price from the investee s latest financing round, the performance of the investee in relation to its own operating targets and its business plan, the investee s revenue and cost trends, the investee s liquidity and cash position, including its cash burn rate, and market acceptance of the investee s products and services. From time to time, the Company may consider third party evaluations or valuation reports. The Company also considers new products and/or services that the investee may have forthcoming, any significant news specific to the investee, the investee s competitors and/or industry and the outlook of the overall industry in which the investee operates. In the event the Company s judgments change as to other-than temporary declines in value, the Company may record an impairment loss, which could have an adverse impact on its results of operations. During the quarter ended September 30, 2008, the Company recorded $1,590,000 in other-than-temporary losses on its investment in Qualigen. This amount is included in other income/(expense) on the consolidated statements of income.

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Note 5 Balance sheet information

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

Inventories

	September 30, 2008	December 31, 2007
Raw materials and supplies	$ 6,023	$ 7,774
Work in process	26,203	23,829
Finished goods	21,015	16,937
	$ 53,241	$ 48,540

Property, plant and equipment, net

	September 30, 2008	December 31, 2007
Land	$ 18,804	$ 13,862
Building	80,426	69,946
Machinery and equipment	150,203	139,871
Building improvements	34,288	32,614
Furniture and fixtures	16,205	16,146
Construction in-progress	11	181
Property, plant and equipment, at cost	299,937	272,620
Less accumulated depreciation and amortization	(160,383)	(143,127)
Property, plant and equipment, net	$ 139,554	$ 129,493

License, manufacturing access fees and other assets, net

	September 30, 2008	December 31, 2007
Patents	$ 13,860	$ 17,304
Purchased intangible assets	33,636	33,636
License and manufacturing access fees	64,507	53,326
Investment in Molecular Profiling Institute, Inc.		2,500
Investment in Qualigen, Inc.	5,403	6,993
Other assets	4,010	3,911
License, manufacturing access fees and other assets, at cost	121,416	117,670
Less accumulated amortization	(63,048)	(59,474)
License, manufacturing access fees and other assets, net	$ 58,368	$ 58,196

In January 2008, Caris Diagnostics completed the acquisition of Molecular Profiling Institute, Inc. Pursuant to this sale transaction, the Company s equity interest in Molecular Profiling was converted into approximately $4,400,000 of

proceeds, of which $4,100,000 was received in January 2008 and the remaining $300,000 was placed into an escrow fund established to satisfy the Company s pro-rata share of indemnification obligations under the Caris/Molecular Profiling merger agreement. The Company recorded a $1,600,000 gain associated with the initial $4,100,000 received in January 2008, and will record the remaining gain if and when any funds are released to the Company from escrow.

In May 2008, pursuant to the Company s supply and purchase agreement with F. Hoffman-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc. (together referred to as Roche), upon the first commercial sale of its CE-marked APTIMA human papillomavirus (HPV) assay in Europe, the Company paid Roche $10,000,000 in manufacturing access fees. Prior to and including May 2008, the Company s original payment to Roche of $20,000,000 was being amortized to research and development (R&D) expense. Beginning in June 2008, the additional payment of $10,000,000 and any unamortized amounts remaining from the original payment are being amortized to cost of product sales.

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In June 2008, the Company recorded an impairment charge for the net capitalized balance of $3,496,000 under its license agreement with Corixa Corporation. This charge is included in R&D expense on the consolidated statements of income. Under the license agreement, the Company was granted exclusive rights to several licenses and pending patents, including AMACR, to develop, manufacture and sell in-vitro, nucleic acid and antibody based assays for the prostate cancer market. The amount of license fees paid to Corixa was initially capitalized based on the Company s assessment at that time of the alternative future uses of the assets, including the Company s initial intent to commercialize the AMACR marker. The Company retains the right to sublicense any of the markers acquired. The Corixa intellectual property was being amortized to R&D expense based upon the estimated life of the underlying patents acquired. In the second quarter of 2008, a series of events indicated that future alternative uses of the capitalized intangible asset were unlikely and that recoverability of the asset through future cash flows was not considered likely enough to support continued capitalization. These second quarter 2008 indicators of impairment included decisions on the Company s planned commercial approach for oncology diagnostic products, the completion of a detailed review of the intellectual property suite acquired from Corixa, including the Company s assessment of the proven clinical utility for a majority of the related markers, and the potential for near term sublicense income that could be generated from the intellectual property acquired.

In September 2008, the Company recorded $1,590,000 in other-than-temporary losses on its investment in Qualigen. This amount is included in other income/(expense) on the consolidated statements of income. See Note 4 for more information.

Note 6 Short-term investments

The Company s short-term investments include tax advantaged municipal securities with a minimum Moody s credit rating of A3 and a minimum Standard & Poor s credit rating of A-. As of September 30, 2008, the Company did not hold auction rate securities. The Company s investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At September 30, 2008, the Company s portfolios had an average term of two years and an average credit quality of AA2 as defined by Moody s.

The following is a summary of short-term investments as of September 30, 2008 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal securities	$ 482,618	$ 2,009	$ (3,500)	$ 481,127

The following table shows the estimated fair values and gross unrealized losses for 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 as of September 30, 2008 (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Municipal securities	$ 268,674	$ (3,278)	$ 11,156	$ (222)

The net unrealized losses on the Company s investments in municipal securities were primarily caused by market forces resulting from a recent and significant sell off of securities by large holders, such as insurance companies and financial institutions, as they were forced to increase their cash reserve positions. Yields for high-quality short-term municipal paper have risen, which have negatively impacted the Company s portfolios, which have an average term of two years. The Company s current valuation is related to this liquidity impact and is not based on the credit worthiness of the securities held by the Company. 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, 2008, since the Company has the ability and intent to hold those investments until a recovery of fair value, which may be at maturity. Gross realized gains from the sale of short-term investments were $34,000 and less than $1,000 for the three month periods ended September 30, 2008 and 2007, respectively, and $440,000 and less than $1,000 for the nine month periods ended September 30, 2008 and 2007, respectively. Gross realized losses from the sale of short-term investments were $31,000 and $53,000 for the three and nine month periods ended September 30, 2008, respectively, and $13,000 for both the three and nine month periods ended September 30, 2007.

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Note 7 Income tax

The Company currently estimates that its annual effective tax rate for 2008 will be approximately 33% to 34%, which includes the benefit of the reinstated federal research credit. This is an increase from the prior year effective tax rate of approximately 23%, as the Company s effective tax rate in 2007 significantly benefited from the settlement of tax audits.

As of September 30, 2008, the Company had total gross unrecognized tax benefits of $5,567,000. 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 $4,251,000. Material tax filings subject to future examination are the Company s California returns filed for the 2005 through 2007 tax years, and the U.S. federal returns filed for the 2006 and 2007 tax years.

Note 8 Stockholders equity

Changes in stockholders equity for the nine months ended September 30, 2008 were as follows (in thousands):

Balance at December 31, 2007	$ 738,040
Net income	85,814
Other comprehensive loss, net	(2,553)
Proceeds from the issuance of common stock	16,059
Purchase of common stock by board members	103
Purchase of common stock through ESPP	1,789
Cancellation of restricted stock awards	(283)
Repurchase and retirement of restricted stock for payment of taxes	(1,309)
Repurchase and retirement of common stock	(9,992)
Stock-based compensation charges	15,296
Excess tax benefit from stock-based compensation	2,510
Balance at September 30, 2008	$ 845,474

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, 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,	
	2008	2007	2008	2007
Net income	$ 29,078	$ 17,251	$ 85,814	$ 65,728
Change in net unrealized (loss) / gain on investments	(950)	1,466	(2,475)	1,015
Foreign currency translation adjustment	(162)	(440)	(78)	(429)
Other comprehensive (loss) / income, net	(1,112)	1,026	(2,553)	586

Comprehensive income	$ 27,966	$ 18,277	$ 83,261	$ 66,314

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Stock options

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	5,518	$ 40.86		
Granted	892	59.38		
Exercised	(499)	32.20		
Cancelled	(210)	49.24		
Outstanding at September 30, 2008	5,701	44.19	5.6	$ 63,482
Exercisable at September 30, 2008	3,403	$ 35.99	5.2	$ 59,653

The Company also had an aggregate of 271,073 shares of restricted stock and 80,000 shares of deferred issuance restricted stock awards outstanding as of September 30, 2008 that have not been reflected in the table above.

Stock Repurchase Program

In August 2008, the Company s Board of Directors authorized the repurchase of up to $250,000,000 of the Company s common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the third quarter of 2008, the Company repurchased and retired approximately 180,000 shares under this program for $10,000,000. When stock is repurchased and retired, the amount paid in excess of par value is recorded to additional paid-in capital.

Note 9 Contingencies

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

Digene Corporation

In December 2006, Digene Corporation (Digene) filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution of the American Arbitration Association in New York (ICDR). 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 between the Company and Roche 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 commenced on October 27, 2008.

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 matters will be resolved in favor of the Company.

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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a safe harbor for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, intends, estimates, could, should, would, continue, seeks or anticipates, or other similar words, includ the negative. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. We assume no obligation to update any forward-looking statements.

The following information should be read in conjunction with our September 30, 2008 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, 2007 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, 2007. 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, 2007.

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 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 25 years of research and development experience in nucleic acid detection, 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 throughout the world.

We have achieved strong growth since 2002 in both revenues and earnings, primarily due to the success of our clinical diagnostic products for sexually transmitted diseases, or STDs, and 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, or Chiron, we manufacture blood screening products, while Novartis is responsible for marketing, sales and service of those products, which Novartis sells under its trademarks.

Recent Events

Financial Results

Product sales for the third quarter of 2008 were $108.3 million, compared to $97.4 million in the same period of the prior year, an increase of 11%. Total revenues for the third quarter of 2008 were $121.2 million, compared to $101.7 million in the same period of the prior year, an increase of 19%. Net income for the third quarter of 2008 was $29.1 million ($0.53 per diluted share), compared to $17.2 million ($0.31 per diluted share) in the same period of the prior year, an increase of 69%.

Product sales for the first nine months of 2008 were $323.5 million, compared to $278.5 million in the same period of the prior year, an increase of 16%. Total revenues for the first nine months of 2008 were $363.6 million, compared to $304.1 million in the same period of the prior year, an increase of 20%. Net income for the first nine months of 2008 was $85.8 million ($1.56 per diluted share), compared to $65.7 million ($1.21 per diluted share) in the same period of the prior year, an increase of 31%. Net income in the first nine months of 2007 benefited from a one-time tax benefit of $8.7 million, or $0.16 per diluted share.

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Stock Repurchase Program

In August 2008, our Board of Directors authorized the repurchase of up to $250.0 million of our common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the third quarter of 2008, we repurchased and retired approximately 180,000 shares under this program for $10.0 million.

Voluntary Counterbid to Acquire Innogenetics

In June 2008, following a bid by Solvay Pharmaceuticals, we launched a conditional counterbid to acquire 100% of the outstanding shares, warrants and convertible bonds of Innogenetics NV, a Belgian molecular diagnostics company, for approximately 215 million. On July 9, 2008, Solvay Pharmaceuticals submitted a higher bid to acquire Innogenetics and we formally withdrew our counterbid. Included in our general and administrative expenses for the first nine months of 2008 are approximately $2.0 million of costs associated with our counterbid to acquire Innogenetics.

Corporate Collaborations

In June 2008, 3M Corporation, or 3M, discontinued our collaboration to develop rapid, molecular tests for healthcare-associated infections, or HCAIs, due to technical incompatibilities between our NAT technologies and 3M s proprietary microfluidics instrument platform. Under the terms of the discontinued agreement, we were responsible for assay development, which 3M funded. 3M also agreed to pay us milestones based on technical and commercial progress. We earned the first of these milestones, related to assay feasibility, in the fourth quarter of 2007. Based on the termination of the agreement, in June 2008 we recorded $2.7 million in collaborative research revenue that was previously deferred. The agreement requires 3M to pay us costs incurred to wind down the collaboration, which we anticipate we will receive in the fourth quarter of 2008.

In January 2008, Millipore Corporation commenced commercialization of the first MilliPROBE assay, developed under our industrial testing collaboration, which targets the bacterium *Pseudomonas aeruginosa* and is designed as an in-process, early warning system to provide faster, more effective detection of *Pseudomonas aeruginosa* in purified water used during drug production. The assay was designed to ensure a higher degree of water quality throughout manufacturing processes where the contaminant can be a serious quality and safety concern. We believe faster detection will enable biopharmaceutical manufacturers to reduce downstream processing risks, optimize product yields and improve final product quality.

Product Development

In August 2008, the Food and Drug Administration, or FDA, approved our triplex assay, Procleix Ultrio, to screen donated blood, plasma, organs and tissues for HBV in individual blood donations or in pools of up to 16 blood samples on the enhanced semi-automated system, or eSAS, and on the fully automated, high-throughput TIGRIS system. The FDA had previously approved the assay to screen donated blood for HIV-1 and HCV.

In May 2008, we launched in Europe our APTIMA HPV assay, a highly specific molecular diagnostic test to detect high-risk strains of HPV, which are associated with cervical cancer. The APTIMA HPV assay has been CE-marked for use on the fully automated, high-throughput TIGRIS system and our semi-automated Direct Tube Sampling, or DTS, system, and is currently available for sale in 13 European Union countries.

In March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. The investigational APTIMA HPV assay is an amplified nucleic acid test that detects 14 high-risk HPV types that are associated with cervical cancer. More specifically, the assay detects two messenger RNAs, or mRNAs, that are made in higher amounts when HPV infections progress toward cervical cancer. We believe that targeting these mRNAs may more accurately identify women at higher risk of having, or developing, cervical cancer than competing assays that target HPV DNA. We expect to enroll approximately 7,000 women in the trial. Actual enrollment, however, may vary based on the prevalence of cervical disease among women in the trial. The trial enrollment and testing are expected to take approximately two years. The APTIMA HPV assay is designed to run on our fully automated, high-throughput TIGRIS instrument system, and on our future medium-throughput instrument platforms.

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Final Payment Received in Litigation Settlement

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

Pursuant to the Settlement Agreement, Bayer paid us an initial license fee of $5.0 million in August 2006. Siemens, as assignee of Bayer, paid us $10.3 million as a one-time royalty on January 31, 2007 and $16.4 million as a one-time royalty on January 31, 2008. As a result of these royalty payments, Siemens rights to the patents subject to the Settlement Agreement are fully paid-up and royalty free.

Pursuant to the Settlement Agreement, we obtained certain contract and patent rights to distribute qualitative HIV-1 and HCV tests through October 2010. We also obtained an option to extend our rights through the life of certain HIV-1 and HCV patents. The option also permits us to elect to extend our rights to future instrument systems (but not to the TIGRIS instrument). We are required to exercise the option prior to the expiration of the existing rights in October 2010 and, if exercised, pay a $1.0 million fee.

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 consolidated 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 2008 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, 2007, except for the items discussed below.

Adoption of recent accounting pronouncements

SFAS No. 157

Effective January 1, 2008, we adopted Statement of Financial Accounting Standards No. 157, Fair Value Measurements, or SFAS No. 157, for financial assets and liabilities measured at fair value. SFAS No. 157 defines fair value, expands disclosure requirements around fair value and specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

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This hierarchy requires us to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. A financial instrument s categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of our valuation methodologies used for instruments measured at fair value. Where appropriate, the description includes details of the valuation models, the key inputs to those models, as well as any significant assumptions.

Available-for-sale securities

Our available-for-sale securities are comprised of tax advantaged municipal securities and money market funds. When available, we generally use quoted market prices to determine fair value, and classify such items in Level 1. If quoted market prices are not available, prices are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals. We classify such items in Level 2. For the quarter ended September 30, 2008, based on current market conditions and evolving interpretation of SFAS No. 157, we determined that municipal securities previously classified as Level 1, should be classified as Level 2. Because Level 1 inputs are those that have identical securities traded on an active market, and these individual securities have varying maturities and are more comparable to similar securities traded on a market that is not active, we determined that a Level 2 classification is more appropriate. The change in classification in no way indicates a decrease in the underlying value of the assets. In addition, money market funds were added to the table with Level 1 or Level 2 classification based on the availability of quoted market prices. At September 30, 2008, we reported $6.9 million and $495.8 million of assets measured at fair value on a recurring basis in Level 1 and 2, respectively.

Equity investment in private company

In 2006, we invested in Qualigen, Inc., or Qualigen, a private company. The valuation of investments in non-public companies requires significant management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such assets. Our equity investments in private companies are valued initially based upon the transaction price under the cost method of accounting. Such instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (for example, when there is evidence of impairment). At September 30, 2008, we reported $5.4 million of assets measured at fair value on a non-recurring basis in Level 3 of the fair value hierarchy.

We record impairment charges when we believe an investment has experienced a decline that is other-than-temporary. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. Future adverse changes in market conditions or poor operating results of investees could result in losses or an inability to recover the carrying value of the investments, thereby possibly requiring impairment charges in the future. When assessing investments in private companies for an other-than-temporary decline in value, we consider such factors as, among other things, the share price from the investee s latest financing round, the performance of the investee in relation to its own operating targets and its business plan, the investee s revenue and cost trends, the investee s liquidity and cash position, including its cash burn rate, and market acceptance of the investee s products and services. From time to time, we may consider third party evaluations or valuation reports. We also consider new products and/or services that the investee may have forthcoming, any significant news specific to the investee, the investee s competitors and/or industry and the outlook of the overall industry in which the investee operates. In the event our judgments change as to other-than temporary declines in value, we may record an impairment loss, which could have an adverse impact on our results of operations. During the quarter ended September 30, 2008, we recorded $1.6 million in other-than-temporary losses on our investment in Qualigen. This amount is included in other income/(expense) on the consolidated statements of income.

SFAS No. 159

Effective January 1, 2008, we adopted SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115, or SFAS No. 159, which expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued

debt. Other eligible items include firm commitments for financial instruments that otherwise would not be

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recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred (e.g., debt issue costs). The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. During the first nine months of 2008, we did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

EITF Issue No. 07-3

Effective January 1, 2008, we adopted Emerging Issues Task Force Issue No. 07-3, Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF Issue No. 07-3. EITF Issue No. 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. There was no material financial statement impact as a result of adoption.

Results of Operations

(Dollars in millions)	**Three Months Ended September 30,**				**Nine Months Ended September 30,**			
			$	**%**			**$**	**%**
	2008	**2007**	**Change**	**Change**	**2008**	**2007**	**Change**	**Change**
Product Sales	$ 108.3	$ 97.4	$ 10.9	11%	$ 323.5	$ 278.5	$ 45.0	16%
As a percent of total revenues	89%	96%			89%	91%		

Our primary source of revenue comes from product sales, which consist primarily of 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. The blood screening assays and instruments we manufacture 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.

Product sales increased 11% in the third quarter of 2008 compared to the same period of the prior year. The $10.9 million increase was primarily attributed to $7.2 million in higher APTIMA assay sales and $6.6 million in higher blood screening assay sales, partially offset by a $2.3 million decrease in instrumentation sales and a $1.3 million decrease in PACE product sales.

Diagnostic product sales, including assay, instrument, and ancillary sales, represented $55.6 million, or 51% of product sales, in the third quarter of 2008, compared to $51.8 million, or 53% of product sales in the third quarter of 2007. This $3.8 million increase was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions, market share gains we attribute to the superior clinical performance of our assay and the availability of our fully automated TIGRIS instrument. Overall APTIMA growth was partially offset by a $1.3 million decrease in our PACE product as customers continue to convert to the more sensitive amplified APTIMA product line. In general, the price of our amplified APTIMA test is twice that of our non-amplified PACE product, thus the conversion from PACE to APTIMA drives an overall increase in product sales even if underlying testing volumes

remain the same.

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Blood screening related sales, including assay, instrument, and ancillary sales, represented $52.7 million, or 49% of product sales in the third quarter of 2008, compared to $45.6 million, or 47% of product sales in the third quarter of 2007. This $7.1 million increase was principally attributed to the March 2007 approval and commercial pricing of our WNV assay for use on the TIGRIS instrument, as well as international expansion of Procleix Ultrio sales by Novartis. In addition, we estimate that $1.8 million of the growth in the third quarter of 2008 over the third quarter of 2007 was related to foreign currency gains associated with favorable exchange rates on revenues collected under our collaboration with Novartis. Novartis is responsible for the billing and collection of revenues under our collaboration and many of the customer contracts and billings are accounted for in local currencies, primarily the Euro. Novartis translates these revenues into U.S. dollars and submits them to us in U.S. dollars, thus creating the favorable impact. Our share of blood screening revenues is based upon sales of assays by Novartis, on blood donation levels and the related price per donation. In the third quarter of 2008, United States blood donation volumes screened using the Procleix blood screening family of assays were relatively consistent with 2007 levels, as was the related pricing.

Product sales increased 16% in the first nine months of 2008 compared to the same period of the prior year. The $45.0 million increase was primarily attributed to $25.9 million in higher blood screening assay sales and $20.9 million in higher APTIMA assay sales, partially offset by a $4.7 million decrease in PACE product sales as customers continue to convert to the more sensitive amplified APTIMA product line.

Diagnostic product sales, including assay, instrument, and ancillary sales, represented $165.3 million, or 51% of product sales, in the first nine months of 2008, compared to $149.5 million, or 54% of product sales in the first nine months of 2007. This $15.8 million increase was primarily driven by volume gains in our APTIMA product line as the result of PACE conversions, market share gains we attribute to the superior clinical performance of our assay and the availability of our fully automated TIGRIS instrument. Overall APTIMA growth was partially offset by a $4.7 million decrease in our PACE product as customers continue to convert to the more sensitive amplified APTIMA product line. In the first nine months of 2008, APTIMA sales were approximately 87% of our STD product sales versus PACE sales of 13%. In the first nine months of 2007, APTIMA represented 81% of STD product sales, and PACE 19%. Average pricing in the first nine months of 2008 related to our APTIMA products decreased approximately 5% from the first nine months of 2007 primarily related to strong unit growth in our corporate account sector.

Blood screening related sales, including assay, instrument, and ancillary sales, represented $158.2 million, or 49% of product sales, in the first nine months of 2008, compared to $129.0 million, or 46% of product sales in the first nine months of 2007. This $29.2 million increase was principally attributed to the March 2007 approval and commercial pricing of our WNV assay for use on the TIGRIS instrument, as well as international expansion of Procleix Ultrio sales by Novartis. In the first nine months of 2008, United States blood donation volumes screened using the Procleix blood screening family of assays were relatively consistent with 2007 levels, as was the related pricing. International revenues increased as the Procleix Ultrio product further penetrated international markets. Included in the blood screening results for the first nine months of 2008 was a one-time $2.6 million benefit related to an adjustment to service costs previously deducted by Novartis prior to arriving at our net share of revenue under the collaboration. In addition, we estimate that $5.2 million of the growth in the first nine months of 2008 over the first nine months of 2007 was related to foreign currency gains associated with favorable exchange rates on revenues collected under our collaboration with Novartis.

(Dollars in millions)	**Three Months Ended September 30,**				**Nine Months Ended September 30,**			
	2008	**2007**	**$ Change**	**% Change**	**2008**	**2007**	**$ Change**	**% Change**
Collaborative Research Revenue	$ 11.3	$ 3.1	$ 8.2	265%	$ 18.5	$ 11.2	$ 7.3	65%
As a percent of total revenues	9%	3%			5%	4%		

We recognize collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned or reimbursable costs are incurred related to those agreements. Negotiated

monthly contracted amounts are earned in relative proportion to the performance required under the contracts. Non-refundable license fees are recognized over the related performance period or at the time that we have satisfied all performance obligations. Milestone payments are recognized as revenue upon the achievement of specified milestones. In addition, we record as collaborative research revenue shipments of blood screening products in the United States and other countries in which the products have not received regulatory approval. This is done because restrictions apply to these products prior to FDA marketing approval in the United States and similar approvals in foreign countries.

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.

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Collaborative research revenue increased 265% in the third quarter of 2008, compared to the same period of the prior year. The $8.2 million increase was primarily due to the $10.0 million milestone payment received from Novartis based on the FDA s approval of our TIGRIS instrument system for use with our Ultrio assay, partially offset by $0.8 million in lower funding revenues from the United States Army Medical Research and Material Command for PCA3 as that contract expired in the fourth quarter of 2007, and a $0.6 million decrease in funding from 3M related to our food testing and healthcare-associated infection collaborations that were discontinued in November 2007 and June 2008, respectively.

Collaborative research revenue increased 65% in the first nine months of 2008, compared to the same period of the prior year. The $7.3 million increase was primarily due to the $10.0 million milestone payment received from Novartis based on the FDA s approval of our TIGRIS instrument system for use with our Ultrio assay, and an increase of $3.8 million from 3M for the development of rapid nucleic acid tests to detect certain dangerous healthcare-associated infections. This collaboration with 3M was discontinued in June 2008. These increases were partially offset by $2.8 million in lower funding revenues from the United States Army Medical Research and Material Command for PCA3 as that contract expired in the fourth quarter of 2007, a $1.8 million decrease in funding revenues from Novartis for Ultrio assay development as that program nears completion, and a $1.2 million decrease in funding from 3M related to our food testing program that was discontinued in November 2007.

Collaborative research revenue tends to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative research revenues, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate additional collaborative research revenues depends, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners and the advancement of related collaborative research and development. These relationships may not be established or maintained and current collaborative research revenue may decline.

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
Royalty and License Revenue	$ 1.6	$ 1.2	$ 0.4	33%	$ 21.6	$ 14.4	$ 7.2	50%
As a percent of total revenues	1%	1%			6%	5%		

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.

Royalty and license revenue increased 33% in the third quarter of 2008 compared to the same period of the prior year. The $0.4 million increase was primarily the result of higher blood plasma royalties from Novartis and higher royalties from Beckton Dickinson based on an increase in net sales of the Becton Dickinson assay for the detection of vaginitis and vaginosis which uses certain of our proprietary technologies for targeting RNA sequences.

Our royalty and license revenue in the first nine months of each of 2008 and 2007 consisted primarily of settlement payments received from Siemens, as assignee Bayer ($16.4 million in 2008 and $10.3 million in 2007). Siemens has now paid all amounts due to us under the Settlement Agreement, and thus these payments will not recur in future periods. The $7.2 million increase in royalty and license revenue during the first nine months of 2008 compared to the same period of the prior year was primarily the result of $6.1 million in higher amounts received from Bayer under the Settlement Agreement, $0.9 million in higher blood plasma royalties from Novartis, and $0.4 million in higher

royalties from Becton Dickinson.

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

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(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
Cost of Product Sales	$ 30.7	$ 31.8	$ (1.1)	(4)%	$ 95.8	$ 91.2	$ 4.6	5%
Gross profit margin as a percent of product sales	72%	67%			70%	67%		

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.

Cost of sales decreased 4% in the third quarter of 2008, compared to the same period of the prior year. Of this $1.1 million decrease, $2.9 million was attributed to favorable manufacturing variances primarily related to increased production volumes and $1.9 million was attributed to lower instrument sales and instrument related costs. These decreases were partially offset by $1.9 million attributed to increased shipments of blood screening products and $1.7 million attributed to increased APTIMA sales.

Cost of sales increased 5% in the first nine months of 2008, compared to the same period of the prior year. Of this $4.6 million increase, $5.8 million was attributed to increased shipments of blood screening products, $4.8 million was attributed to increased APTIMA sales, $1.7 million was attributed to higher instrument sales and instrument related costs, and $1.2 million was attributed to increased amortization of capitalized intangible assets. These increases were partially offset by favorable manufacturing variances of $8.1 million, primarily related to increased production volumes, and $0.7 million in lower stock-based compensation expense.

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.

Our gross profit margin as a percentage of product sales increased to 72% in the third quarter of 2008, and to 70% in the first nine months of 2008, from 67% in both comparable periods of 2007. The increase in gross profit margin percentage was principally attributed to increased sales of the blood screening Ultrio and WNV assays by Novartis and increased APTIMA sales, which have higher margins, and favorable changes in production volumes, partially offset by increased instrument sales, which have lower margins, and instrument related costs.

A portion of our blood screening revenues is from sales of TIGRIS instruments to Novartis, which totaled $9.9 million and $6.2 million during the first nine months of 2008 and 2007, 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.

Certain blood screening markets are trending from pooled testing of large numbers of donor samples to smaller pool sizes. A greater number of tests will be required in markets where smaller pool sizes are required. Under our collaboration agreement with Novartis, we bear the cost of manufacturing blood screening assays. The greater number of tests required for smaller pool sizes 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 adoption of smaller pool sizes. We have already observed this trend with respect to certain sales internationally. 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, because we do not know the ultimate selling price that Novartis will charge to the end user or the degree to which smaller pool size testing will be adopted across the markets in which we sell our products.

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(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
Research and Development	$ 24.5	$ 27.6	$ (3.1)	(11)%	$ 77.0	$ 72.8	$ 4.2	6%
As a percent of total revenues	20%	27%			21%	24%		

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 development of new products and technologies in collaboration with our partners. R&D spending is 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 blood screening products, further development of our TIGRIS instrument, initial development of Panther, our fully automated system for low and mid-volume laboratories, assay integration activities for Panther, as well as for the development and validation of assays for PCA3, HPV and for industrial applications; however, we expect our R&D expenses as a percentage of total revenues to decline in future years.

R&D expenses decreased 11% in the third quarter of 2008, compared to the same period of the prior year. The $3.1 million decrease was primarily due to a $4.7 million decrease in development lot activity, primarily related to timing of our HPV diagnostic product, and a $0.5 million decrease in professional fees for consultant services no longer utilized in 2008. These decreases were partially offset by an increase of $1.5 million in clinical evaluations and outside services associated with our Procleix Ultrio yield studies, for which we filed a supplemental Biologic License Application, or BLA, with the FDA in February 2008, as well as our license agreement with Xceed Molecular USA, Inc., or Xceed, pursuant to which we were granted rights to access certain flow-thru chip technology of Xceed.

R&D expenses increased 6% in the first nine months of 2008, compared to the same period of the prior year. The $4.2 million increase was primarily due to a $5.1 million increase in clinical evaluations and outside services associated with our Procleix Ultrio yield studies, for which we filed a supplemental BLA with the FDA in February 2008, HPV trials which began in March 2008, as well as our license agreement with Xceed, a $3.5 million impairment charge associated with our Corixa license agreement, and an increase of $0.8 million in salaries and personnel-related expenses. These increases were partially offset by a $4.6 million decrease in development lot activity, primarily related to timing of our HPV diagnostic product, and a $0.8 million decrease in professional fees for consultant services no longer utilized in 2008.

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
Marketing and Sales	$ 10.7	$ 9.6	$ 1.1	12%	$ 34.1	$ 28.6	$ 5.5	19%
As a percent of total revenues	9%	9%			9%	9%		

Our marketing and sales expenses include salaries and other personnel-related expenses, promotional expenses, and outside services. Marketing and sales expenses increased 12% in the third quarter of 2008, compared to the same period of the prior year. The $1.1 million increase was primarily due to a $0.9 million increase in salaries and personnel-related expenses resulting from the hiring of additional employees.

Marketing and sales expenses increased 19% in the first nine months of 2008, compared to the same period of the prior year. The $5.5 million increase was primarily due to a $2.8 million increase in salaries and personnel-related expenses resulting from the hiring of additional employees, a $1.0 million increase in spending for marketing studies and promotional activities related to both our HPV and PCA3 products in Europe, a $0.8 million increase in travel expenses as a result of our increased international market development efforts, and a $0.4 million increase in

professional fees.

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
General and Administrative	$ 12.9	$ 11.4	$ 1.5	13%	$ 38.5	$ 34.7	$ 3.8	11%
As a percent of total revenues	11%	11%			11%	11%		

Our general and administrative, or G&A, expenses include expenses for finance, legal, strategic planning and business development, public relations and human resources. G&A expenses increased 13% in the third quarter of 2008, compared to the same period of the prior year. The $1.5 million increase was primarily the result of a $0.9 million increase in salaries and personnel-related expenses, and a $0.8 million increase in professional fees.

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G&A expenses increased 11% in the first nine months of 2008, compared to the same period of the prior year. The $3.8 million increase was primarily the result of a $2.5 million increase in professional fees and a $1.3 million increase in bank charges, partially attributable to our counterbid to acquire Innogenetics, as well as a $1.4 million increase in salaries and personnel-related expenses, partially offset by a $1.0 million decrease in relocation expenses associated with senior level personnel hired in the prior year.

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
Interest income	$ 4.1	$ 3.3	$ 0.8	24%	$ 12.3	$ 8.9	$ 3.4	38%
Interest expense				N/M				N/M
Other income / (expense)	(1.9)		(1.9)	N/M	(0.7)	(0.3)	(0.4)	133%
Total Other Income, net	$ 2.2	$ 3.3	$ (1.1)	(33)%	$ 11.6	$ 8.6	$ 3.0	35%

The $0.8 million increase in interest income in the third quarter of 2008 from the comparable period of 2007 was primarily a result of higher average balances of our short-term investments. The $1.9 million increase in other expense during the third quarter of 2008 from the comparable period of 2007 was primarily the result of an impairment charge of $1.6 million related to our investment in Qualigen.

The $3.4 million increase in interest income in the first nine months of 2008 from the comparable period of 2007 was primarily a result of higher average balances of our short-term investments. Included in the $0.4 million net increase in other expense was a $1.6 million gain resulting from the sale of our equity interest in Molecular Profiling Institute, Inc., which was offset by an impairment charge of $1.6 million related to our investment in Qualigen.

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008	2007	$ Change	% Change	2008	2007	$ Change	% Change
Income Tax Expense	$ 15.5	$ 7.4	$ 8.1	109%	$ 44.0	$ 19.7	$ 24.3	123%
As a percent of income before tax	35%	30%			34%	23%		

Income tax expense, as a percentage of pre-tax income, increased in the third quarter of 2008 from the comparable period of 2007 as the prior year period benefited from a favorable adjustment upon completion of our 2006 federal tax return. In the first nine months of 2008, income tax expense increased as a percentage of pre-tax income from the comparable period of 2007. This increase was primarily due to an $8.7 million tax benefit recorded in the second quarter of 2007 as a result of an IRS settlement on our U.S. federal audit of 2003 and 2004 tax returns. We estimate our annual effective tax rate for 2008 will be 33% to 34%, which includes the reinstatement of the federal research credit.

Liquidity and capital resources

	September 30, 2008	December 31, 2007
	(In thousands)	
Cash, cash equivalents and short-term investments	$ 555,493	$ 433,494
Working capital	$ 616,265	$ 518,408

Current ratio	12:1	14:1

The primary objectives of our investment policy are liquidity and safety of principal. Consistent with these objectives, investments are made with the goal of achieving the highest rate of return. The policy places emphasis on securities of high credit quality, with restrictions placed on maturities and concentration by security type and issue. Our short-term investments include tax advantaged municipal securities with a minimum Moody s credit rating of A3 and a minimum Standard & Poor s credit rating of A-. As of September 30, 2008, we did not hold auction rate securities. Our investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At September 30, 2008, our portfolios had an average term of two years and an average credit quality of AA2 as defined by Moody s.

Our working capital at September 30, 2008 increased $97.9 million from December 31, 2007, primarily due to an increase in our short-term investments purchased with cash generated from operations. Days sales outstanding, or DSO, decreased to 24 days at September 30, 2008 from 31 days at December 31, 2007, primarily due to a customer payment received prior to its due date. Days sales in inventory decreased to 97 days at September 30, 2008 from 153 days at December 31, 2007 due to lower average inventory levels for the period ended September 30, 2008 resulting from increased sales volume.

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	Nine Months Ended September 30,		
	2008	2007	$ Change
	(In thousands)		
Cash provided by (used in):			
Operating activities	$ 159,019	$ 74,560	$ 84,459
Investing activities	(169,475)	(148,572)	20,903
Financing activities	9,057	52,712	(43,655)
Purchases of property, plant and equipment (included in investing activities above)	$ (30,530)	$ (17,674)	$ 12,856

Our primary source of liquidity has been cash from operations, which includes the collection of accounts and other receivables related to product sales, collaborative research agreements, and royalty and license fees. Our primary short-term cash needs, which are subject to change, include continued R&D spending to support new products, costs related to commercialization of products and purchases of instrument systems, primarily TIGRIS, for placement with our customers. Certain R&D costs may be funded under collaboration agreements with partners.

The $84.5 million increase in net cash provided by operating activities during the first nine months of 2008 compared to the same period of the prior year was primarily due to $20.1 million in higher net income, a $27.3 million decrease in accounts receivable due to collections from our customers and collaborative partners, an $17.5 million decrease in income tax payable primarily due to benefits from the completion of income tax audits, a $13.6 million decrease in prepaid expenses related to upfront fees paid in the first nine months of 2007 for the purchase of TIGRIS instruments, a $10.5 million reduction in tax benefits from stock-based compensation, a $5.2 million decrease in other accrued expenses related to accruals for HPV materials received and warranty settlements in 2007, a $6.9 million increase in inventories, and a $6.3 million increase in accounts payable balances related to increased cost of sales and timing of payments.

The $20.9 million increase in net cash used in investing activities during the first nine months of 2008 compared to the same period of the prior year was principally attributed to a $12.9 million increase in capital expenditures and a payment of $10.0 million to Roche associated with commercialization of our CE-marked HPV product. For 2008, we expect capital spending to increase from 2007 levels due primarily to the purchase of our blood screening facility, which closed in the first quarter of 2008.

The $43.7 million decrease in net cash provided by financing activities during the first nine months of 2008 compared to the same period of the prior year was principally attributed to a $22.9 million decrease in proceeds from the exercise of stock options and the associated $10.5 million decrease in excess tax benefits. We receive cash from the exercise of employee stock options and proceeds from the sale of common stock pursuant to the employee stock purchase plan, or ESPP. We also used $10.0 million to repurchase and retire approximately 180,000 shares of our common stock under our stock repurchase program. We expect fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock, along with other factors.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2009, under which we may borrow up to $10.0 million, subject to a borrowing base formula, at the bank s prime rate, or at LIBOR plus 1.0%. At September 30, 2008, we did not have any amounts outstanding under the bank line and we have not taken advances against the line since inception. The line of credit agreement requires us to comply with various financial and restrictive covenants. As of September 30, 2008, we were in compliance with all covenants.

We believe that our available cash balances, anticipated cash flows from operations, proceeds from stock option exercises and available line of credit will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to covenants

restricting our operations.

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

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Contractual obligations and commercial commitments

Our contractual obligations due for purchase commitments and collaborative agreements as of September 30, 2008 were as follows (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Material purchase commitments [1]	$ 23,434	$ 6,492	$ 16,942	$	$
Collaborative commitments [2]	2,850	100	2,125	250	375
Total [3]	$ 26,284	$ 6,592	$ 19,067	$ 250	$ 375

(1) 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 $23.4 million total, $21.3 million is expected to be used to purchase TIGRIS instruments, of which we anticipate that approximately $10.4 million of instruments will be sold to Novartis. Not included in the $23.4 million is $9.6 million expected to be used to purchase validation, pre-production

and production instruments, and associated tooling, pursuant to our development agreement with Stratec for the Panther instrument 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.

(2) In addition to the minimum payments due under our collaborative agreements, we may be required to pay up to $12.2 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.

(3) 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 blood screening assays to Novartis, and Novartis is obligated to purchase all of the assay quantities 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.

Liabilities associated with uncertain tax positions, currently estimated at $5.6 million (including interest), are not included in the table above as we cannot reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

Additionally, we have liabilities for deferred employee compensation which totaled $4.0 million at September 30, 2008. 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 leave the Company. At this time, we cannot reasonably predict when these events may occur. Liabilities for deferred employee compensation are offset by deferred compensation assets, which totaled $3.8 million at September 30, 2008.

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.

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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 the fair market value of our current investment balance by approximately $10.0 million. While changes in our interest rates may affect the fair market 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 market 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 British pound 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 (loss)/income 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, 2008 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, 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. Based on international blood screening product sales during the first nine months of 2008, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $6.5 million annually. We do not enter into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks. We believe that our business operations are not exposed to market risk relating to commodity prices.

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, 2008.

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, 2008 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

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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 9 Contingencies, 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 from time to time 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, 2007. In addition, we have removed a risk factor relating to our TIGRIS instrument and added a risk factor relating to current economic conditions.

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, oncology and industrial products, as well as some of our clinical diagnostic products, have a relatively limited sales history, which limits our ability to project future sales, prices and the sales cycles accurately. In addition, we base our internal projections of 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.

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Our financial performance may be adversely affected by current global economic conditions.*

Our business depends on the overall demand for our products and on the economic health of our current and prospective customers. Our projected revenues and operating results are based on assumptions concerning certain levels of customer demand. We have not experienced recent declines in overall blood screening or clinical diagnostics customer purchases as a result of current economic conditions, however, a continued weakening of the global and domestic economy, or a reduction in customer spending or credit availability, could result in downward pricing pressures, delayed or decreased purchases of our products and longer sales cycles. Furthermore, during challenging economic times our customers may face issues gaining timely access to sufficient credit, which could result in an impairment of their ability to make timely payments to us. If that were to occur, we may be required to increase our allowance for doubtful accounts. If economic and market conditions in the United States or other key markets persist, spread, or deteriorate further, we may experience adverse effects on our business, operating results and financial condition.

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 blood screening products we manufacture. Commercial product sales to Novartis accounted for 44% of our total revenues for the first nine months of 2008 and 46% of total revenues for 2007. As of September 30, 2008, we believe our collaboration agreement with Novartis will terminate in 2013. The collaboration agreement may be 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.

In February 2001, we commenced an arbitration proceeding against Chiron (now Novartis) 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.

In July 2008, we were notified that certain blood screening assays manufactured by us for Novartis and sold outside of the United States might have been improperly stored at a Novartis warehouse in Singapore. Following our established quality system, an investigation for product performance was initiated. On August 12, 2008, we determined that, based on the results of our investigation to date, we could not fully assess the potential impact of these improper storage conditions on the ultimate performance of the product without conducting additional stability testing. As a result, we and Novartis agreed that products previously delivered to customers from this warehousing facility should be replaced and the appropriate field actions were initiated with customers and the regulatory authorities in the affected countries. While we do not expect to incur charges in connection with this event, we devoted considerable time and attention to rectifying the issues resulting from the improper storage conditions and events such as this may harm our commercial reputation.

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. In August 2006, we 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 should be terminated, as we requested, except as to the qualitative HCV assays and as to quantitative Analyte Specific Reagents, or ASRs, for HCV. As Bayer s assignee, 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 collaboration 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 HIV-1 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.

We rely upon bioMérieux for distribution of certain of our products in most of Europe and Australia, 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.

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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. In November 2007, for example, 3M informed us that it no longer intended to fund our collaboration to develop rapid molecular assays for the food testing industry. We and 3M subsequently terminated this agreement. In June 2008, 3M discontinued our collaboration to develop assays for healthcare-associated infections.

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 2013. The collaboration agreement may be 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. 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 current 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.

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. 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 new instrument platforms, 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, market and medical practice 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.

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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 along in the development process than we are with respect to such assays and instrumentation.

In the market for blood screening products, the primary competitor to our collaboration with Novartis is Roche, which received FDA approval of its PCR-based NAT tests for blood screening in December 2002. Our collaboration with Novartis also competes 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 collaboration blood screening products also may compete with viral inactivation or reduction technologies and blood substitutes.

Novartis, with whom we have a collaboration agreement for blood screening products, retains certain rights to grant licenses of the patents related to HCV to third parties in blood screening using NAT. Prior to its merger with Novartis, Chiron granted an HCV license to Roche in the blood screening and clinical diagnostics fields. Chiron also granted an HCV license in the clinical diagnostics field to Bayer Healthcare LLC (now Siemens), together with the right to grant certain additional 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. If Novartis grants additional licenses in blood screening or Siemens grants additional licenses in clinical diagnostics, further competition will be created for sales of HCV assays and these licenses could affect the prices that can be charged for our products.

We have 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 have collaboration agreements to develop NAT products for detecting microorganisms in selected water applications, and for microbiological and virus monitoring in the biotechnology and pharmaceutical manufacturing industries. 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.

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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. For example, most pharmaceutical manufacturers rely on culture testing of their manufacturing systems, and may be unwilling to switch to molecular testing like that used in our recently launched MilliPROBE product to detect *Pseudomonas aeruginosa.* 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 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, we may incur recall and product liability costs. 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.

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 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 from specification in any raw material we receive could significantly delay 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 HPV 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 our 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

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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, 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.

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.

We currently offer ASRs for use in the detection of PCA3 mRNA and for use in the detection of the parasite *Trichomonas vaginalis.* We also have developed an ASR for quantitative HCV testing that Siemens provides to Quest Diagnostics. The FDA restricts the sale of these products to clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform high complexity testing and also restricts the types of products that can be sold as ASRs. The FDA has recently published draft guidance for ASRs that define the types of products that can be sold as ASRs. Under the terms of this guidance and the ASR Manufacturer Letter issued in June 2008 by the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA, it may be more challenging for us to market some of our ASR products and we may be required to terminate those ASR product sales, conduct clinical studies and make submissions of our products to the FDA for clearance or approval.

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 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.

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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 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 gross profit margin percentage on the sale of blood screening assays will decrease upon the implementation of smaller pool size testing.*

We currently receive revenues from the sale of 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 blood screening assays under our collaboration 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.

Certain blood screening markets are trending from pooled testing of large numbers of donor samples to smaller pool sizes. A greater number of tests will be required in markets where smaller pool sizes are required. Under our collaboration agreement with Novartis, we bear the cost of manufacturing blood screening assays. The greater number of tests required for smaller pool sizes 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 adoption of smaller pool sizes. We have already observed this trend with respect to certain sales internationally. 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, because we do not know the ultimate selling price that Novartis would charge to the end user or the degree to which smaller pool size testing will be adopted across the markets in which we sell our products.

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. Revenues from our blood screening collaboration with Novartis accounted for 48% of our total revenues for the first nine months of 2008 and 49% of our total revenues for 2007. Our blood screening collaboration with Novartis is largely dependent on two large customers in the United States, The American Red Cross and America s Blood Centers, although we did not receive any revenues directly from those entities. Novartis was our only customer that accounted for greater than 10% of our total revenues for the first nine months of 2008. Various state and city public health agencies accounted for an aggregate of 8% of our total revenues in the first nine months of 2008 and 10% of total revenues for the fiscal year 2007. 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.

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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 460 United States and foreign patents covering our products and technologies as of September 30, 2008, 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 December 8, 2025 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, continued 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 and inventions 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 and inventions agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market and execute our business strategies.

The diagnostic products industry has a history of patent and other intellectual property litigation, and we have been and may continue to be involved in costly intellectual property lawsuits.*

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. From time-to-time in the ordinary course of business we receive communications from third parties calling our attention to patents or other intellectual property rights owned by them, with the implicit or explicit suggestion that we may need to acquire a license of such rights. We have faced in the past, and may face in the future, patent infringement lawsuits by companies that control patents for products and services similar to ours or other lawsuits alleging infringement by us of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management s attention from other business concerns. The cost of this litigation could adversely affect our results of operations, making us less

profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

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Recently, we have been involved in a number of patent-related disputes with third parties. In December 2006, Digene Corporation filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution (the IDCR) 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 our supply and purchase agreement with Roche 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 commenced on October 27, 2008.

Pursuant to our June 1998 collaboration agreement with Novartis, we hold certain rights in the blood screening and clinical diagnostics fields under patents originally issued to Novartis covering the detection of HIV. We sell a qualitative HIV test in the clinical diagnostics field and we manufacture tests for HIV for use in the blood screening field, which Novartis sells under Novartis brands and name. 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 Novartis. The first interference was between Novartis and the National Institutes of Health, or NIH, and pertained to 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 pertained 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 invented the subject matter at issue prior to NIH and Novartis. We are also informed that Novartis and NIH subsequently filed actions in the United States District Court for the District of Columbia challenging the decisions of the Patent and Trademark Office in the patent interference cases. From November 2007 through June 2008, the parties engaged in settlement negotiations and then notified the court that they had signed a memorandum of understanding prior to the negotiation of final, definitive settlement documents. On May 16, 2008, we signed a license agreement with Institut Pasteur concerning Institut Pasteur s intellectual property for the molecular detection of HIV, covering products manufactured and sold through, and under, our brands or name. On June 27, 2008, the parties to the pending litigation in the United States District Court for the District of Columbia informed the court that they were unable to reach a final, definitive agreement and intended to proceed with litigation. There can be no assurances as to the ultimate outcome of the interference litigation and no assurances as to how the outcome of the interference litigation may affect the patent rights licensed from Institut Pasteur, or Novartis right to sell the HIV blood screening tests.

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

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

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

As of September 30, 2008, we had approximately $230.6 million of long-lived assets, including $14.0 million of capitalized software, net of accumulated amortization, relating to our TIGRIS instrument, goodwill of $18.6 million, a $5.4 million investment in Qualigen, Inc., and $53.0 million of capitalized license and manufacturing access fees, patents, purchased intangibles and other long term assets. Additionally, we had $75.0 million of land and buildings, $16.7 million of building improvements, and $47.9 million of equipment and furniture and fixtures. The substantial

majority of our long-lived assets are located in the United States. 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.

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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.

In June 2008, we recorded an impairment charge for the net capitalized balance of $3.5 million under our license agreement with Corixa Corporation. In the second quarter of 2008, a series of events indicated that future alternative uses of the capitalized intangible asset were unlikely and that recoverability of the asset through future cash flows was not considered likely enough to support continued capitalization. These second quarter 2008 indicators of impairment included decisions on our planned commercial approach for oncology diagnostic products, the completion of a detailed review of the intellectual property suite acquired from Corixa, including our assessment of the proven clinical utility for a majority of the related markers, and the potential for near term sublicense income that could be generated from the intellectual property acquired.

In the quarter ended September 30, 2008, we recorded a $1.6 million other-than-temporary loss relating to our investment in Qualigen, Inc. In making this determination, we considered a number of factors, including, among others, the share price from the company s latest financing round, the performance of the company in relation to its own operating targets and business plan, the company s revenue and cost trends, the company s liquidity and cash position, including its cash burn rate, market acceptance of the company s products and services, new products and/or services that the company may have forthcoming, any significant news specific to the company, the company s competitors and industry, the outlook of the overall industry in which the company operates and a third party valuation report.

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 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 seek to 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.

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, including as a result of current economic conditions, we may be unable to address gaps in our product offerings or improve our technology, particularly through acquisitions or investments.

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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. 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.

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.

Our sales to international markets are subject to additional risks.*

Sales of our products outside the United States accounted for 23% of our total revenues for the first nine months of 2008 and 21% of our total revenues for 2007. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 69% of our international revenues in the first nine months of 2008 and 76% in fiscal year 2007. Novartis has responsibility for the international distribution of collaboration blood screening products.

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We encounter risks inherent in international operations. We expect a significant portion of our sales growth, especially with respect to blood screening products, to come from expansion in international markets. If the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. Our international sales also may be limited or disrupted by:

the imposition of government controls,

export license requirements,

economic and political instability,

price controls,

trade restrictions and tariffs,

differing local product preferences and product requirements, and

changes in foreign medical reimbursement and coverage policies and programs.

In addition, we anticipate that requirements for smaller pool sizes 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.

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. Diagnocure Inc., from whom we have an exclusive license to the PCA3 gene marker for prostate cancer, recently asserted that we may have lost market exclusivity because of a failure to meet a milestone under our license and collaboration agreement. We disagree with Diagnocure s assertion and we have commenced discussions with Diagnocure on the issue, but we can give no assurance that this matter will be resolved in our favor.

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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.

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 personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop new products or enhance existing products in a timely manner, sell products to our customers or manage our business effectively.

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

As part of our business strategy, we intend to pursue acquisitions of complementary businesses and enter into technology licensing arrangements. We also intend to pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. We have limited experience with respect to acquiring other companies. Any future acquisitions by us 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. For example, we recently withdrew our counterbid to acquire Innogenetics NV as a result of a higher offer made by Solvay Pharmaceuticals. Prior to withdrawing our bid, our management devoted substantial time and attention to the proposed transaction. Further, we nonetheless remain liable for transaction costs, including legal, accounting and other fees.

Managing 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 includes significant 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.

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

If a natural or man-made disaster strikes our manufacturing facilities, we will be unable to manufacture our products for a substantial amount of time and our sales will decline.

We manufacture substantially all of our 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. The wildfires in San Diego in October 2007 required that we temporarily shut down our facility for the manufacture of blood screening products. 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 our stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management. The provisions of our amended and restated certificate of incorporation and amended and restated bylaws, among other things:

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

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

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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 enterprise resource planning software system to replace our various legacy systems. To more fully realize the potential of this system, we are continually reassessing and upgrading 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.

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.

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Item 2. Unregistered Sales 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, 2008 Repurchase program [1]		$		$
July 1-31, 2008 Employee transactions [2]				
August 1-31, 2008 Repurchase program [1]				250,000,000
August 1-31, 2008 Employee transactions [2]	13,742	60.27		
September 1-30, 2008 Repurchase program [1]	180,100	55.48	180,100	240,000,000
September 1-30, 2008 Employee transactions [2]	67	56.35		
Total Repurchase program [1]	180,100	55.48	180,100	
Total Employee transactions [2]	13,809	$ 60.26		$

[1] In August 2008, our Board of Directors authorized the repurchase of up to $250.0 million of our common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum

number of shares to be repurchased under the program.

(2) During the third quarter of 2008, we repurchased and retired 13,809 shares of our common stock, at an average per share price of $60.26, 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, 2008, we had an aggregate of 271,073 shares of restricted stock and 80,000 shares of deferred issuance restricted stock awards outstanding.

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Item 6. Exhibits

Exhibit Number	Description
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)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(4)	Certificate of Elimination of Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)	Specimen common stock certificate.
10.107	Form of Employment Agreement Executive Team (as approved in September 2008)
10.108	Form of Employment Agreement Vice Presidents (as approved in September 2008)
31.1	Certification dated October 31, 2008, 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 October 31, 2008, 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 October 31, 2008, 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 October 31, 2008, 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.

(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.

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SIGNATURES

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

GEN-PROBE INCORPORATED

DATE: October 31, 2008

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

DATE: October 31, 2008

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