GEN PROBE INC
Form 10-Q
November 03, 2010

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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, 2010

OR

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission File Number 000-49834
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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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	Smaller Reporting Company o

(Do not check if a smaller reporting company)

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 29, 2010, there were 48,207,723 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, 2010 (unaudited)	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents, including restricted cash of $20 and $17 at September 30, 2010 and December 31, 2009, respectively	$ 149,060	$ 82,616
Marketable securities	273,503	402,990
Trade accounts receivable, net of allowance for doubtful accounts of $316 and $516 at September 30, 2010 and December 31, 2009, respectively	57,306	55,305
Accounts receivable other	4,624	4,707
Inventories	60,826	61,071
Deferred income tax	15,615	13,959
Prepaid income tax		7,317
Prepaid expenses	11,667	14,526
Other current assets	4,036	4,708
Total current assets	576,637	647,199
Marketable securities, net of current portion	44,889	15,472
Property, plant and equipment, net	157,645	157,437
Capitalized software, net	12,690	12,560
Goodwill	122,500	122,680
Purchased intangibles, net	101,257	108,015
License, manufacturing access fees and other assets, net	112,686	64,822
Total assets	$ 1,128,304	$ 1,128,185
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 13,667	$ 20,455
Accrued salaries and employee benefits	20,845	24,775
Other accrued expenses	14,224	24,755
Income tax payable	2,167	
Short-term borrowings	240,228	240,127
Deferred revenue	1,690	3,527
Total current liabilities	292,821	313,639
Non-current income tax payable	6,198	5,958
Deferred income tax	21,042	23,220
Deferred revenue, net of current portion	2,219	1,978
Other long-term liabilities	6,457	16,215
Commitments and contingencies		
Stockholders equity:		

Preferred stock, $0.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized, 48,086,123 and 49,143,798 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	5	5
Additional paid-in capital	197,123	242,615
Accumulated other comprehensive income	2,801	4,616
Retained earnings	599,638	519,939
Total stockholders equity	799,567	767,175
Total liabilities and stockholders equity	$ 1,128,304	$ 1,128,185

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,	
	2010	2009	2010	2009
Revenues:				
Product sales	$ 128,313	$ 118,951	$ 391,616	$ 348,289
Collaborative research revenue	3,405	2,000	10,810	5,862
Royalty and license revenue	847	1,753	4,207	5,281
Total revenues	132,565	122,704	406,633	359,432
Operating expenses:				
Cost of product sales (excluding acquisition-related intangible amortization)	42,146	36,345	129,118	107,939
Acquisition-related intangible amortization	2,201	1,136	6,616	2,250
Research and development	27,433	27,475	84,218	78,542
Marketing and sales	13,872	13,477	44,476	38,547
General and administrative	11,510	15,234	41,208	46,903
Total operating expenses	97,162	93,667	305,636	274,181
Income from operations	35,403	29,037	100,997	85,251
Other income (expense):				
Investment and interest income	3,197	4,676	10,364	19,680
Interest expense	(586)	(588)	(1,681)	(1,465)
Gain on contingent consideration	1,513		7,595	
Other income (expense), net	267	210	(82)	(827)
Total other income, net	4,391	4,298	16,196	17,388
Income before income tax	39,794	33,335	117,193	102,639
Income tax expense	12,398	11,139	37,494	34,881
Net income	$ 27,396	$ 22,196	$ 79,699	$ 67,758
Net income per share:				
Basic	$ 0.57	$ 0.45	$ 1.63	$ 1.33
Diluted	$ 0.56	$ 0.44	$ 1.61	$ 1.31
Weighted average shares outstanding:				
Basic	48,254	49,343	48,796	50,848
Diluted	48,679	49,865	49,257	51,482

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,	
	2010	**2009**
Operating activities		
Net income	$ 79,699	$ 67,758
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	34,111	29,468
Amortization of premiums on investments, net of accretion of discounts	6,819	4,050
Stock-based compensation	18,538	17,743
Excess tax benefit from employee stock-based compensation	(891)	(1,186)
Deferred revenue	(1,528)	(249)
Deferred income tax	(3,708)	(1,318)
Gain on contingent consideration	(7,595)	
Loss on disposal of property and equipment	603	82
Changes in assets and liabilities:		
Trade and other accounts receivable	(2,127)	(4,379)
Inventories	204	2,325
Prepaid expenses	2,861	(1,675)
Other current assets	877	2,156
Goodwill		856
Other long-term assets	(353)	(3,608)
Accounts payable	(6,177)	(2,985)
Accrued salaries and employee benefits	(3,884)	1
Other accrued expenses	(2,230)	1,672
Income tax payable	10,863	(4,718)
Other long-term liabilities	(268)	733
Net cash provided by operating activities	125,814	106,726
Investing activities		
Proceeds from sales and maturities of marketable securities	404,350	410,700
Purchases of marketable securities	(311,450)	(338,976)
Proceeds from sale of property, plant and equipment	23	
Purchases of property, plant and equipment	(22,090)	(22,284)
Purchases of capitalized software	(2,081)	(576)
Purchases of intangible assets, including licenses and manufacturing access fees	(1,639)	(918)
Net cash paid for business combinations		(123,713)
Cash paid for investment in Pacific Biosciences	(50,000)	
Cash paid for investment in DiagnoCure and related license fees	(500)	(5,500)
Other	(1,007)	(175)
Net cash provided by (used in) investing activities	15,606	(81,442)
Financing activities		

Repurchase and retirement of common stock	(88,079)	(174,847)
Proceeds from issuance of common stock and employee stock purchase plan	24,699	5,961
Payment of contingent consideration	(10,000)	
Repurchase and retirement of restricted stock for payment of taxes	(1,252)	(923)
Excess tax benefit from employee stock-based compensation	891	1,186
Borrowings, net		238,450
Net cash (used in) provided by financing activities	(73,741)	69,827
Effect of exchange rate changes on cash and cash equivalents	(1,235)	1,506
Net increase in cash and cash equivalents	66,444	96,617
Cash and cash equivalents at the beginning of period	82,616	60,122
Cash and cash equivalents at the end of period	$ 149,060	$ 156,739

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, 2010, and for the three and nine month periods ended September 30, 2010 and 2009, 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, 2010.

These unaudited interim consolidated financial statements and related footnotes should be read in conjunction with the audited consolidated financial statements and related footnotes contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2009.

Certain prior year amounts have been reclassified to conform to the current year presentation.

Principles of Consolidation

These unaudited interim consolidated financial statements include the accounts of Gen-Probe as well as its wholly owned subsidiaries. The Company does not have any interests in variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

In April 2009, the Company completed its acquisition of Tepnel Life Sciences plc (Tepnel), a United Kingdom (UK) based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd. Tepnel s transplant diagnostics and genetic testing businesses have been included in the Company s clinical diagnostic operations beginning in April 2009. While Tepnel s research products and services business represents a new area of business for the Company, the activities of this business were immaterial to the Company s overall operations during the first nine months of 2010 and 2009.

In October 2009, the Company acquired Prodesse, Inc. (Prodesse), a privately-held Wisconsin corporation, now known as Gen-Probe Prodesse, Inc. Prodesse develops molecular diagnostic products for a variety of infectious disease applications. Prodesse s results of operations have been included in the Company s clinical diagnostic operations beginning in October 2009.

The Company translates the financial statements of its non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates on intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders equity under the caption Accumulated other comprehensive income. These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported in the consolidated financial statements. These estimates include assessing the collectability of accounts receivable, recognition of revenues, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; liabilities associated with employee benefit costs and contingent consideration; inventories; and goodwill and long-lived assets, including patent costs, capitalized software, acquired intangible assets and licenses and manufacturing access fees. Actual results could differ from those estimates.

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Marketable Securities

The primary objectives of the Company s marketable security investment portfolio are liquidity and safety of principal. Investments are made with the goal of achieving the highest rate of return consistent with these two objectives. The Company s investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Marketable securities are carried at fair value, with unrealized gains and losses, net of tax, reported as a separate component of stockholders equity under the caption Accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in Investment and interest income.

Realized gains and losses, and declines in value deemed to be other-than-temporary on marketable securities, are included in Investment and interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in Investment and interest income.

The Company periodically reviews its marketable securities for other-than-temporary declines in fair value below the cost basis, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. When assessing marketable securities for other-than-temporary declines in value, the Company considers factors including: the significance of the decline in value compared to the cost basis; the underlying factors contributing to a decline in the prices of securities in a single asset class; how long the market value of the investment has been less than its cost basis; any market conditions that impact liquidity; the views of external investment managers; any news or financial information that has been released specific to the investee; and the outlook for the overall industry in which the investee operates.

The Company does not consider its investments in marketable securities with a current unrealized loss position to be other-than-temporarily impaired at September 30, 2010 because the Company does not intend to sell the investments and it is more likely than not that the Company will not be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at September 30, 2010 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of current portion, reflecting the Company s current intent and ability to hold such investments to maturity. The Company has determined that its investments in marketable securities should be classified as available-for-sale.

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 have 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 Vaccines and Diagnostics, Inc. (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 the Company s ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized.

Generally, the Company provides its instrumentation to its clinical diagnostics customers 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 amount it charges for its diagnostic assays. The depreciation costs associated with an instrument

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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 Gen-Probe s and United States Food and Drug Administration (FDA) specifications, and is shipped fully assembled. Customer acceptance of the Company s clinical diagnostic 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 shipments of its blood screening products in the United States and other countries in which the products have not received regulatory approval as collaborative research revenue. 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 records revenue on its research products and services in the period during which the related costs are incurred, or services are provided. This revenue consists of outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

The Company analyzes each element of its collaborative arrangements to determine the appropriate revenue recognition. The Company recognizes revenue on up-front payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. Revenue arrangements with multiple deliverables are divided into separate units of accounting if (i) the delivered item has stand-alone value, (ii) the vendor has objective and reliable evidence of the fair value of the undelivered item(s), and (iii) the customer has a general right of return relative to the delivered item(s) and delivery or performance of the undelivered item(s) is probable and substantially within the vendor s control. All of these criteria must be met in order for a delivered item to be accounted for as a separate unit.

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 applicable 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 its consolidated balance sheets.

Royalty and license 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.

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Stock-based Compensation

Stock-based compensation expense for awards granted to employees and directors under the Company s equity incentive plans is measured based on estimated grant date fair values. These awards include stock options, restricted stock, deferred issuance restricted stock, performance stock awards and shares purchasable under the Company s employee stock purchase plan (ESPP). The value of awards, adjusted for estimated forfeitures, is recognized as expense over the requisite service period.

Stock-based compensation expense for restricted stock, deferred issuance restricted stock and performance stock awards is measured based on the closing fair market value of the Company s common stock on the date of grant. The Company uses the following weighted average assumptions within the Black-Scholes model to estimate the fair value of stock options and shares purchasable under the ESPP for the three and nine month periods ended September 30, 2010 and 2009:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	**2009**	**2010**	**2009**
Stock Option Plans				
Risk-free interest rate	1.5%	2.2%	2.1%	2.0%
Volatility	32%	35%	32%	35%
Dividend yield				
Expected term (years)	4.4	4.4	4.4	4.3
Resulting average fair value	$ 12.97	$ 12.29	$ 12.79	$ 12.64
ESPP				
Risk-free interest rate	0.2%	2.3%	0.2%	1.8%
Volatility	21%	34%	24%	40%
Dividend yield				
Expected term (years)	0.5	0.5	0.5	0.5
Resulting average fair value	$ 9.62	$ 10.65	$ 9.63	$ 11.42

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, 2010 and 2009 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	**2009**	**2010**	**2009**
Cost of product sales	$ 946	$ 753	$ 2,817	$ 2,356
Research and development	1,783	1,954	5,313	5,422
Marketing and sales	682	943	2,319	2,481
General and administrative	2,788	2,688	8,089	7,484
Total	$ 6,199	$ 6,338	$ 18,538	$ 17,743

The Company s unrecognized stock-based compensation expense as of September 30, 2010, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards is presented in the table as follows (in thousands, except number of years):

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Awards	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense as of September 30, 2010
Options	2.5	$ 27,017
Employee stock purchase plan	0.2	82
Performance stock awards	2.4	875
Restricted stock	1.8	4,891
Deferred issuance restricted stock	2.0	1,405
Total		$ 34,270

Net Income Per Share

Basic earnings per share is computed using the two-class method. Under the two-class method, net income is allocated to common stock and participating securities. The Company s restricted stock, deferred issuance restricted stock and performance stock awards meet the definition of participating securities. Basic net income per share is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share 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 because their effect is anti-dilutive. Potentially dilutive securities totaling approximately 4,065,000 and 4,291,000 shares for the three month periods ended September 30, 2010 and 2009, respectively, and 4,390,000 and 3,680,000 shares for the nine month periods ended September 30, 2010 and 2009, respectively, were excluded from the calculations of diluted earnings per share (EPS) below because of their anti-dilutive effect.

The following table sets forth the computation of basic and diluted EPS for the three and nine month periods ended September 30, 2010 and 2009 (in thousands, except per share amounts):

	Three Months Ended September 30,					
	2010			2009		
	Income	Weighted Average Shares Outstanding	Per Share Amount	Income	Weighted Average Shares Outstanding	Per Share Amount
Net income	$ 27,396			$ 22,196		
Less: Earnings allocated to unvested stockholders	(99)			(82)		
Basic EPS						
Distributable income available to common stockholders	27,297	48,254	$ 0.57	22,114	49,343	$ 0.45

Effect of dilutive securities:								
Add back: Undistributed earnings allocated to unvested stockholders		99				82		
Dilutive stock options			425				522	
Less: Undistributed earnings reallocated to unvested stockholders		(99)				(82)		
Diluted EPS	**Common stock**	$ 27,297	48,679	$ 0.56	$ 22,114	49,865	$	0.44

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	Nine Months Ended September 30,					
	2010			2009		
	Income	Weighted Average Shares Outstanding	Per Share Amount	Income	Weighted Average Shares Outstanding	Per Share Amount
Net income	$ 79,699			$ 67,758		
Less: Earnings allocated to unvested stockholders	(327)			(265)		
Basic EPS						
Distributable income available to common stockholders	79,372	48,796	$ 1.63	67,493	50,848	$ 1.33
Effect of dilutive securities:						
Add back: Undistributed earnings allocated to unvested stockholders	327			265		
Dilutive stock options		461			634	
Less: Undistributed earnings reallocated to unvested stockholders	(324)			(262)		
Diluted EPS Common stock	$ 79,375	49,257	$ 1.61	$ 67,496	51,482	$ 1.31

Pending Adoption of Recent Accounting Pronouncements

Accounting Standards Update 2010-06

In January 2010, the Financial Accounting Standards Board (FASB) amended Accounting Standards Codification (ASC) Topic 820, Fair Value Measurements and Disclosures, to require reporting entities to make new disclosures about recurring and nonrecurring fair value measurements, including significant transfers into and out of Level 1 and Level 2 fair value measurements and information about purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. Except for the detailed Level 3 roll forward disclosures, the guidance was effective January 1, 2010. The new disclosures about purchases, sales, issuances, and settlements in the roll forward activity for Level 3 fair value measurements are effective for the Company as of January 1, 2011. Early adoption is permitted. The adoption of this standard will not impact the Company s financial position or results of operations.

Accounting Standards Update 2010-17

In March 2010, the FASB ratified the final consensus that offers an alternative method of revenue recognition for milestone payments. The guidance states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance will be effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted, provided that the revised guidance is applied retrospectively to the beginning of the year of adoption. The guidance may be applied retrospectively or prospectively for milestones achieved after the adoption date. The Company is currently evaluating prospective adoption and determining the effects, if any, the adoption of this guidance will have on its consolidated financial statements.

Accounting Standards Update 2009-13

In September 2009, the FASB revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables

contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for the Company s fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially

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modified arrangements. The Company is currently evaluating early prospective adoption and determining the effects, if any, the adoption of this guidance will have on its consolidated financial statements.

Note 2 Business Combinations

The acquisitions described below were accounted for as business combinations and, accordingly, the Company has included the results of operations of the acquired entities in its consolidated statements of income from the date of acquisition. Neither separate financial statements nor pro forma results of operations have been presented because the acquisitions did not meet the quantitative materiality tests under Regulation S-X.

Acquisition of Tepnel Life Sciences plc

In April 2009, the Company acquired Tepnel, a UK-based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd., which has two principal businesses, molecular diagnostics and research products and services. As a result of the acquisition, Tepnel became a wholly-owned subsidiary of the Company.

Upon consummation of the acquisition, each issued ordinary share of Tepnel was cancelled and converted into the right to receive 27.1 pence in cash, or approximately $0.40 based on the then applicable Great Britain Pound (GBP) to United States Dollar (USD) exchange rate. In connection with the acquisition, the holders of issued and outstanding Tepnel capital stock, options and warrants received total net cash of approximately £92.8 million, or approximately $137.1 million based on the then applicable GBP to USD exchange rate. The acquisition was financed through amounts borrowed by the Company under a senior secured revolving credit facility established between the Company and Bank of America, N.A. (Bank of America).

The final allocation of the purchase price for the acquisition of Tepnel is as follows (in thousands):

Total purchase price	$ 137,093
Exchange rate differences	(568) [1]
Allocated purchase price	$ 136,525
Net working capital	$ 14,811
Fixed assets	11,352
Goodwill	70,395
Deferred tax liabilities	(14,148)
Other intangible assets	57,497
Liabilities assumed	(3,382)
Allocated purchase price	$ 136,525

[1] Difference caused by exchange rate fluctuations between the date of acquisition and the date funds were wired.

The fair values of the acquired identifiable intangible assets with definite lives are as follows (in thousands):

Patents	$ 294

Software	441
Customer relationships	45,439
Trademarks / trade names	11,323
Total	$ 57,497

The amortization periods for the acquired intangible assets with definite lives are as follows: 10 years for patents, 5 years for software, 12 years for customer relationships, and 20 years for trademarks and trade names. The Company plans to amortize the acquired intangible assets set forth in the table above using the straight line method of amortization. The Company believes that the use of the straight line method is appropriate given the high customer retention rate of the acquired businesses and the historical and projected growth of revenues and related cash flows.

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The Company will monitor and assess the acquired intangible assets and will adjust, if necessary, the expected life, amortization method or carrying value of such assets to best match the underlying economic value.

The fair value assigned to trademarks and trade names has been determined primarily by using the income approach and a variation of the income approach known as the relief from royalty method, which estimates the future royalties which would have to be paid to the owner of the brand for its current use. Tax is deducted and a discount rate is used to state future cash flows to a present value. This is based on the brand in its current use and is based on savings from owning the brand, or relief from royalties that would be paid to the brand owner. The fair value assigned to customer relationships has been determined primarily by using the income approach and a variation of the income approach known as the excess earnings method, which estimates the value of an asset based on discounted future earnings specifically attributed to that asset, that is, in excess of returns for other assets that contributed to those earnings. The fair value assigned to assembled workforce (a component of goodwill) and software has been determined primarily by using the cost approach and a variation of the cost approach known as the cost to recreate method, which represents the cost to recreate the workforce and software at the valuation date. The fair value assigned to patents has been determined primarily by using the income approach and a variation of the income approach known as the discounted cash flow method, which estimates the value based on the present value of the after-tax free cash flows attributable to owning the intangible asset. The discount rates used in these valuation methods range from 12 to 13 percent.

The estimated amortization expense for acquired intangible assets over future periods as of September 30, 2010 is as follows (in thousands):

Years Ending December 31,	
Remainder of 2010	$ 1,017
2011	4,067
2012	4,067
2013	4,067
2014	4,067
Thereafter	29,758
Total	$ 47,043

Acquisition of Prodesse, Inc.

In October 2009, the Company acquired Prodesse, a privately-held Wisconsin corporation, for approximately $60.0 million, subject to a designated pre-closing operating income adjustment. The Company may also be required to make additional cash payments to former Prodesse securityholders of up to an aggregate of $25.0 million based on the achievement of certain specified performance measures, of which $10.0 million was paid in July 2010. Further information regarding the contingent consideration can be found in Note 5 Fair Value Measurements. As a result of the acquisition, Prodesse (which is now known as Gen-Probe Prodesse, Inc.) became a wholly owned subsidiary of the Company. The Company financed the acquisition through existing cash on hand.

The purchase price allocation for the acquisition of Prodesse set forth below is preliminary and subject to change as more detailed analysis is completed and additional information with respect to the fair value of the assets and liabilities acquired becomes available. The Company expects to finalize the purchase price allocation by the fourth quarter of 2010. The preliminary allocation of the purchase price for the Company s acquisition of Prodesse is as follows (in thousands):

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Total purchase price	$ 62,005
Net working capital	$ 10,240
Fixed assets	644
Goodwill	32,981
Deferred tax liabilities	(21,369)
Other intangible assets	58,570
Liabilities assumed	(1,067)
Contingent consideration	(17,994)
Allocated purchase price	$ 62,005

The fair values of the acquired identifiable intangible assets with definite lives are as follows (in thousands):

In-process research and development	$ 1,070
Developed technology	24,500
Customer relationships	31,800
Trademarks / trade names	1,200
Total	$ 58,570

The amortization periods for the acquired intangible assets with definite lives are as follows: 15 years for in-process research and development (to commence upon commercialization of associated product), 12 years for developed technology, 12 years for customer relationships, and 20 years for trademarks and trade names. The Company is amortizing the acquired intangible assets set forth in the table above using the straight line method of amortization. The Company will monitor and assess the acquired intangible assets and will adjust, if necessary, the expected life, amortization method or carrying value of such assets to best match the underlying economic value.

The fair value assigned to trademarks and trade names and developed technology has been determined primarily by using the income approach and a variation of the income approach known as the relief from royalty method, which estimates the future royalties which would have to be paid to the owner of the brand for its current use. Tax is deducted and a discount rate is used to state future cash flows to a present value. This is based on the brand in its current use and is based on savings from owning the brand, or relief from royalties that would be paid to the brand owner. The fair value assigned to in-process research and development and customer relationships has been determined primarily by using the income approach and a variation of the income approach known as the excess earnings method, which estimates the value of an asset based on discounted future earnings specifically attributed to that asset, that is, in excess of returns for other assets that contributed to those earnings. The discount rates used in these valuation methods range from 25 to 30 percent.

In addition to acquiring Prodesse s existing products, the Company also acquired other products that can be classified as next generation products, which are in the process of being developed. Overall, a value of approximately $1.1 million was classified as in-process research and development for the products under development. The Company has incurred a total of approximately $1.6 million in research and development expenses since the acquisition of Prodesse, which includes these development activities related to next generation products. The Company anticipates revenues will be generated from these products starting in late 2010. The Company will commence amortizing the in-process research and development intangible assets upon FDA approval or clearance of these products, as applicable.

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The estimated amortization expense for acquired intangible assets over future periods as of September 30, 2010 is as follows (in thousands):

Years Ending December 31,	
Remainder of 2010	$ 1,188
2011	4,752
2012	4,752
2013	4,752
2014	4,752
Thereafter	34,018
Total	$ 54,214

Changes in Goodwill Resulting From Acquisitions

The $137.1 million purchase price for Tepnel exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company allocated $70.4 million to goodwill. Included in this initial goodwill amount was $14.1 million related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired intangible assets. Prior to finalizing the Company s purchase price allocation for its acquisition of Tepnel in the first quarter of 2010, the Company made a $0.4 million adjustment to the goodwill recognized as part of its acquisition of Tepnel based on additional information received during the period. This adjustment resulted in an increase in the estimated value of an acquired liability, which was paid in April 2010.

The $62.0 million purchase price for Prodesse exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company allocated $33.0 million to goodwill. Included in this initial goodwill amount was $21.4 million related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired intangible assets.

Changes in goodwill for the nine months ended September 30, 2010 were as follows (in thousands):

Goodwill balance as of December 31, 2009	$ 122,680
Changes due to foreign currency translation	(180)
Goodwill balance as of September 30, 2010	$ 122,500

Note 3 Consolidation of UK Operations

Due to the acquisition of Tepnel in April 2009, the Company now has four locations in the UK: Manchester, Cardiff, Livingston, and Abingdon. In order to accommodate the anticipated growth in the business and to optimize expenses, the Company decided to consolidate its UK operations to Manchester and Livingston. This consolidation was communicated internally in May 2010. Consolidation activities related to the employees and facilities were accounted for under ASC Topic 420, Exit or Disposal Costs (ASC 420). The Company estimates that expenses related to this consolidation will total approximately $3.9 million and be incurred over a two year period, as the consolidation will occur in phases. These expenses will include one-time termination costs including severance costs related to the elimination of certain redundant positions, relocation costs for certain key employees, and site closure costs.

During the three months ended September 30, 2010, the Company recorded approximately $0.3 million and $0.2 million of one-time termination costs and one-time site closure costs, respectively. During the nine months ended September 30, 2010, the Company recorded $0.4 million and $0.2 million of one-time termination costs and one-time site closure costs, respectively. These amounts are included in general and administrative expenses in the Company s consolidated statements of income.

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The following table summarizes the restructuring activities accounted for under ASC 420 for the nine months ended September 30, 2010, as well as the remaining restructuring accrual in the consolidated balance sheets at September 30, 2010 (in thousands):

	One-time Termination Costs	One-time Site Closure Costs	Total
Restructuring reserves at December 31, 2009	$	$	$
Charged to expenses	428	233	661
Amounts paid	(198)	(233)	(431)
Restructuring reserves at September 30, 2010	$ 230	$	$ 230

Note 4 Spin-off of Industrial Testing Assets to Roka Bioscience, Inc.

In September 2009, the Company spun-off its industrial testing assets, including the Closed Unit Dose Assay (CUDA) system, to Roka Bioscience, Inc. (Roka), a newly formed private company focused on developing rapid, highly accurate molecular assays for biopharmaceutical production, water and food safety testing, and other applications. In consideration for the contribution of assets, the Company received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis.

In addition to the CUDA system, the Company contributed to Roka other industrial assets and the right to use certain of its technologies and related know-how in certain industrial markets. These markets include biopharmaceutical production, water and food safety testing, veterinary testing, environmental testing and bioterrorism testing. Roka also has rights to develop certain infection control tests for use on the CUDA system.

The Company will receive royalties on any potential Roka product sales, and retains rights to use the CUDA system for clinical diagnostic applications. In addition, the Company is providing contract manufacturing and certain other services to Roka on a transitional basis.

The Company determined that Roka is not a variable interest entity and therefore is not included in the Company s consolidated financial statements.

Note 5 Fair Value Measurements

As discussed in Note 1, in January 2010 the Company adopted updated accounting guidance which requires additional disclosure about the amounts of and reasons for significant transfers into and out of Level 1 and Level 2 fair value measurements. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. Because this accounting standard only requires enhanced disclosure, the adoption of this standard did not impact the Company s financial position or results of operations for the three and nine month periods ended September 30, 2010. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard will require additional disclosure and require an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount.

Fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. There is an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the factors market participants would use in valuing the asset or liability. The guidance establishes three levels of inputs that may be used to measure fair value:

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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.

Assets and liabilities are classified based upon the lowest level of input that is significant to the fair value measurement. The Company reviews the fair value hierarchy on a quarterly basis. Changes in the observations or valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

Set forth below is a description of the Company s valuation methodologies used for assets and liabilities 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 marketable securities include treasury securities, tax advantaged municipal securities, Federal Deposit Insurance Corporation (FDIC) insured corporate bonds and money market funds. When available, the Company generally uses quoted market prices to determine fair value, and classifies such items as 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 as Level 2.

There were no changes to the Company s fair value measurement classifications for its assets and liabilities during the quarter ended September 30, 2010.

The following table presents the Company s fair value hierarchy for assets and liabilities measured at fair value on a recurring basis (as described above) as of September 30, 2010 and December 31, 2009 (in thousands):

	Fair Value Measurements at September 30, 2010			
	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**
Assets:				
Cash equivalents	$	$ 83,442	$	$ 83,442
Marketable securities				
Treasury securities		9,163		9,163
Municipal securities		305,422		305,422
Corporate obligations		3,807		3,807
Total marketable securities		318,392		318,392
Deferred compensation plan assets		5,825		5,825
Total assets at fair value	$	$ 407,659	$	$ 407,659

Liabilities:				
Contingent consideration	$	$	$ 399	$ 399
Deferred compensation plan liabilities		5,782		5,782
Total liabilities at fair value	$	$ 5,782	$ 399	$ 6,181

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	Fair Value Measurements at December 31, 2009			
	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
Assets:				
Cash equivalents	$	$ 13,000	$	$ 13,000
Marketable securities				
Certificates of deposit		1,961		1,961
Municipal securities		324,252		324,252
Corporate obligations		92,249		92,249
Total marketable securities		418,462		418,462
Deferred compensation plan assets		5,671		5,671
Total assets at fair value	$	$ 437,133	$	$ 437,133
Liabilities:				
Contingent consideration	$	$	$ 17,994	$ 17,994
Deferred compensation plan liabilities		5,700		5,700
Total liabilities at fair value	$	$ 5,700	$ 17,994	$ 23,694

For those financial instruments with significant Level 3 inputs, the following table summarizes the activity for the nine months ended September 30, 2010 (in thousands):

Level 3 contingent consideration as of December 31, 2009	$ 17,994
Payment of milestone	(10,000)
Gain included in other income (expense)	(7,595)
Level 3 contingent consideration as of September 30, 2010	$ 399

The range of potential contingent consideration that the Company could pay related to the acquisition of Prodesse was originally between $0 and $25.0 million. This range is tied to multiple performance measures including commercial and regulatory milestones. To the extent these milestones are earned, payments of up to $25.0 million in total will be made. The Company will reassess the fair value of this contingent consideration liability on a quarterly basis. This assessment is based on a calculation that considers the forecasted achievement of the underlying milestones as of the date of determination, as well as the timing of the related cash payments, and then discounts these amounts based on a discount rate the Company determines is appropriate for the underlying milestones.

Based on these calculations, the Company initially recorded $18.0 million as of the date of acquisition as the fair value of this potential contingent consideration liability. In July 2010, the Company received FDA clearance of its

ProFAST + assay, thereby satisfying one of the acquisition-related milestones and triggering a $10.0 million payment to former Prodesse securityholders. The fair value of the remaining contingent consideration was reduced by $7.6 million for the nine months ended September 30, 2010 due to lower anticipated payouts for the related milestones. Future milestone payments, if any, will occur between the first quarter of 2011 and the second quarter of 2012.

Assets and Liabilities Measured at Fair Value on a Non-recurring Basis

Certain assets and liabilities, including cost method investments, are 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. The Company s assets which are evaluated on a non-recurring basis include investments in public and private companies, which are described below.

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Equity Investment in Public Company

In April 2009, the Company made a $5.0 million preferred stock investment in DiagnoCure, Inc. (DiagnoCure), a publicly-held company traded on the Toronto Stock Exchange. The Company s equity investment was initially valued based on the transaction price under the cost method of accounting. The market value of the underlying common stock is the most observable value of the preferred stock, but because there is no active market for these preferred shares the Company has classified its equity investment in DiagnoCure as Level 2 in the fair value hierarchy. The Company s investment in DiagnoCure, which totaled $5.0 million as of September 30, 2010, is included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

Equity Investments in Private Companies

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 initially valued based upon the transaction price under the cost method of accounting. Equity investments in non-public companies are classified as Level 3 in the fair value hierarchy.

In June 2010, in connection with the execution of a collaboration agreement, the Company made a $50.0 million preferred stock investment in Pacific Biosciences of California, Inc. (Pacific Biosciences), a privately-held sequencing company. The Company s investment is included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets. In October 2010, Pacific Biosciences completed an initial public offering of its common stock, which now trades on the NASDAQ Global Select Market under the symbol PACB . As a result of the initial public offering, the Company s preferred stock was converted into common stock. In the future, the Company will measure the fair value of its investment in Pacific Biosciences based on the quoted market price of Pacific Biosciences common stock and classify this investment as a Level 1 item.

In September 2009, the Company spun-off its industrial testing assets to Roka, a newly formed private company. In consideration for the contribution of assets, the Company received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis. The Company s investment in Roka totaled approximately $0.7 million as of September 30, 2010, and is also included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

In 2006, the Company invested in Qualigen, Inc. (Qualigen), a private company. The Company s investment in Qualigen, which totaled approximately $5.4 million as of September 30, 2010, is also included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

The Company records impairment charges when an investment has experienced a decline that is deemed to be 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 many factors, including, but not limited to, the following: 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 effect on its results of operations.

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Note 6 Balance Sheet Information

The following tables provide details of selected balance sheet items as of September 30, 2010 and December 31, 2009 (in thousands):

Inventories

	September 30, 2010	December 31, 2009
Raw materials and supplies	$ 15,801	$ 13,260
Work in process	22,273	23,656
Finished goods	22,752	24,155
Inventories, net	$ 60,826	$ 61,071

Property, Plant and Equipment, Net

	September 30, 2010	December 31, 2009
Land	$ 19,280	$ 19,268
Building	80,108	80,130
Machinery and equipment	186,589	175,885
Building improvements	45,181	42,718
Furniture and fixtures	19,737	17,705
Construction in-progress	1,299	457
Property, plant and equipment, at cost	352,194	336,163
Less: accumulated depreciation and amortization	(194,549)	(178,726)
Property, plant and equipment, net	$ 157,645	$ 157,437

Purchased Intangibles, Net

	September 30, 2010	December 31, 2009
Purchased intangibles, at cost	$ 145,349	$ 145,502
Less: accumulated amortization	(44,092)	(37,487)
Purchased intangibles, net	$ 101,257	$ 108,015

License, Manufacturing Access Fees and Other Assets, Net

	September 30, 2010	December 31, 2009
Patents	$ 19,555	$ 19,042
License and manufacturing access fees	64,133	62,502
Investment in Pacific Biosciences	50,000	

Investment in Qualigen		5,404		5,404
Investment in DiagnoCure		5,000		5,000
Investment in Roka		725		725
Other assets		8,329		7,961
License, manufacturing access fees and other assets, at cost		153,146		100,634
Less: accumulated amortization		(40,460)		(35,812)
License, manufacturing access fees and other assets, net	$	112,686	$	64,822

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Other Accrued Expenses

	September 30, 2010	December 31, 2009
Royalties	$ 2,926	$ 2,907
Research and development	2,909	4,930
Professional fees	2,243	1,175
Marketing	1,006	1,365
Interest	865	726
Warranty	391	334
Current component of contingent consideration	188	8,829
Other	3,696	4,489
Other accrued expenses	$ 14,224	$ 24,755

Note 7 Marketable Securities

The Company s marketable securities include treasury securities, tax advantaged municipal securities and FDIC insured corporate bonds with a minimum Moody s credit rating of A3 or a Standard & Poor s credit rating of A-. As of September 30, 2010, the Company did not hold auction rate securities and has never held any such securities. The Company s investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. As of September 30, 2010, the Company s portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody s.

The following is a summary of the Company s marketable securities as of September 30, 2010 (in thousands):

Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
$ 316,816	$ 1,692	$ (116)	$ 318,392

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, 2010 (in thousands):

Less than 12 Months		More than 12 Months	
Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
$ 54,074	$ (116)	$	$

The unrealized losses on certain of the Company s investments in municipal securities were caused by interest rate increases. At September 30, 2010 and December 31, 2009, the Company had 25 securities and 23 securities, respectively, in an unrealized loss position. 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 investments. The Company does not consider its investments in municipal securities with a current unrealized loss position to be other-than-temporarily impaired at September 30, 2010 because the Company does not intend to sell the investments and it is more likely than not that the Company will not be required to sell the investments before recovery of their amortized cost. However, investments in an unrealized loss position deemed to be temporary at September 30, 2010 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption

Marketable securities, net of current portion, reflecting the Company s current intent and ability to hold such investments to maturity. The Company s investments in municipal securities are classified as available-for-sale.

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The following table shows the current and non-current classification of the Company s marketable securities as of September 30, 2010 and December 31, 2009 (in thousands):

	September 30, 2010	December 31, 2009
Current	$ 273,503	$ 402,990
Non-current	44,889	15,472
Total marketable securities	$ 318,392	$ 418,462

The following table shows the gross realized gains and losses from the sale of marketable securities, based on the specific identification method, for the three and nine month periods ended September 30, 2010 and 2009 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Proceeds from sale of marketable securities	$ 126,754	$ 118,961	$ 408,946	$ 418,698
Gross realized gains	$ 2,261	$ 2,470	$ 6,343	$ 10,985
Gross realized losses	(4)	(12)	(4)	(467)
Net realized gain	$ 2,257	$ 2,458	$ 6,339	$ 10,518

Note 8 Borrowings

In February 2009, the Company entered into a credit agreement with Bank of America, which provided for a one-year senior secured revolving credit facility in an amount of up to $180.0 million that is subject to a borrowing base formula. The revolving credit facility has a sub-limit for the issuance of letters of credit in a face amount of up to $10.0 million. Advances under the revolving credit facility were used to consummate the Company s acquisition of Tepnel and are also available for other general corporate purposes. At the Company s option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America s prime rate and (iii) the London Interbank Offered Rate (LIBOR) plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by the Company. In connection with the credit agreement, the Company also entered into a security agreement, pursuant to which the Company secured its obligations under the credit agreement with a first priority security interest in the securities, cash and other investment property held in specified accounts maintained by Merrill Lynch, Pierce, Fenner & Smith Incorporated, an affiliate of Bank of America. In connection with the execution of the credit agreement with Bank of America, the Company terminated the commitments under its unsecured bank line of credit with Wells Fargo Bank, N.A., effective as of February 27, 2009. There were no amounts outstanding under the Wells Fargo Bank line of credit as of the termination date.

In March 2009, the Company borrowed $170.0 million under the revolving credit facility in anticipation of funding its acquisition of Tepnel. Also in March 2009, the Company and Bank of America amended the credit agreement to increase the amount that the Company can borrow from time to time under the credit agreement from $180.0 million to $250.0 million. In April 2009, the Company borrowed an additional $70.0 million under its revolving credit facility with Bank of America.

In February 2010, the Company entered into a second amendment to its credit agreement with Bank of America, pursuant to which, among other things, the maturity date of the Company s senior secured revolving credit facility was

extended for an additional one-year period. As extended, the credit facility now expires on February 25, 2011. As of September 30, 2010, the total principal amount outstanding under the revolving credit facility was $240.0 million and the interest rate payable on such outstanding amount was approximately 0.86%.

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As a result of the Tepnel acquisition, the Company assumed Tepnel s pre-existing fixed-rate term loan, which accrues interest at an effective rate of 6.6% and is to be repaid in quarterly installments through February 2018. As of September 30, 2010, the outstanding principal amount under this loan was £0.5 million, or $0.8 million based on the exchange rate of £1 to $1.58 as of the balance sheet date. Of this outstanding amount, $0.2 million and $0.6 million was classified as short-term and long-term, respectively, as of September 30, 2010.

Note 9 Income Tax

As of September 30, 2010, the Company had total gross unrecognized tax benefits of $8.4 million. The amount of unrecognized tax benefits (net of the federal benefit for state taxes) that would favorably affect the Company s effective income tax rate, if recognized, was $6.2 million. Material filings subject to future examination are the Company s California returns filed for the 2005 through 2009 tax years, and the Company s U.S. federal returns filed for the 2007 through 2009 tax years.

Note 10 Contingencies

Contingent Consideration

In connection with the Company s acquisition of Prodesse, the Company may be obligated to make certain payments to former Prodesse securityholders of up to $25.0 million. The aggregate fair value of these payments was $0.4 million as of September 30, 2010, and is reflected in the Company s consolidated balance sheets under the captions Other accrued expenses and Other long-term liabilities. In July 2010, the Company received FDA clearance of its ProFAST + assay, thereby satisfying one of the acquisition-related milestones and triggering a $10.0 million payment to former Prodesse securityholders. Future milestone payments, if any, will occur between the first quarter of 2011 and the second quarter of 2012.

Litigation

The Company is a party to the following litigation and may also 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 F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. (collectively, Roche), with the International Centre for Dispute Resolution (ICDR) of the American Arbitration Association in New York. In July 2007, the ICDR arbitrators granted the Company s petition to join the arbitration. Digene s arbitration demand challenged the validity of the February 2005 supply and purchase agreement between the Company and Roche. Under the supply and purchase agreement, Roche manufactures and supplies the Company with human papillomavirus (HPV) oligonucleotide products. Digene s demand asserted, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting the Company an improper sublicense and sought a determination that the supply and purchase agreement is null and void.

In April 2009, following the arbitration hearing, a three-member arbitration panel from the ICDR issued an interim award rejecting all claims asserted by Digene (now Qiagen Gaithersburg, Inc.).

In August 2009, the arbitrators issued their final arbitration award, which confirmed the interim award and also granted the Company s motion to recover attorneys fees and costs from Digene in the amount of approximately $2.9 million. The Company filed a petition to confirm the arbitration award in the U.S. District Court for the Southern District of New York and Digene filed a petition to vacate or modify the award. In August 2010, the court confirmed

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the arbitration award and the Company received the $2.9 million from Digene, which was recorded as an offset to general and administrative expense.

Becton, Dickinson and Company

In October 2009, the Company filed a complaint for patent infringement against Becton, Dickinson and Company (BD) in the U.S. District Court for the Southern District of California. The complaint alleges that BD s Viper XTR™ testing system infringes five of the Company s U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint also alleges that BD s ProbeTec™ Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) deoxyribonucleic acid (DNA) assays used with the Viper XTR testing system infringe two of the Company s U.S. patents covering penetrable caps for specimen collection tubes. Finally, the complaint alleges that BD has infringed the Company s U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified; however, the Company has moved to dismiss this specific claim from the lawsuit, while maintaining all other claims. The complaint seeks monetary damages and injunctive relief. In March 2010, the Company filed a second complaint for patent infringement against BD in the U.S. District Court for the Southern District of California. The complaint alleges that BD s BD MAX System™ (formerly known as the HandyLab Jaguar system) infringes four of the Company s U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint seeks monetary damages and injunctive relief. In June 2010, these two actions were consolidated into a single legal proceeding. There can be no assurances as to the final outcome of the litigation.

Note 11 Stockholders Equity

Changes in stockholders equity for the nine months ended September 30, 2010 were as follows (in thousands):

Balance at December 31, 2009	$ 767,175
Net income	79,699
Other comprehensive income (loss), net	(1,815)
Proceeds from the issuance of common stock and ESPP	24,699
Issuance of common stock to board members	198
Repurchase and retirement of common stock	(88,079)
Repurchase and retirement of restricted stock for payment of taxes	(1,252)
Stock-based compensation	18,051
Excess tax benefit from employee stock-based compensation	891
Balance at September 30, 2010	$ 799,567

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 the Company s 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, for the three and nine month periods ended September 30, 2010 and 2009 were as follows (in thousands):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income, as reported	$ 27,396	$ 22,196	$ 79,699	$ 67,758
Other comprehensive income (loss):				
Foreign currency translation adjustment	3,822	(846)	(530)	2,513
Change in net unrealized gain on available-for-sale securities during the period	(1,753)	(812)	(5,406)	(8,238)
Reclassification adjustments:				
Realized gain on available-for-sale securities, net of tax	1,467	1,598	4,121	6,837
Total other comprehensive income (loss), net	3,536	(60)	(1,815)	1,112
Comprehensive income	$ 30,932	$ 22,136	$ 77,884	$ 68,870

Stock Options

A summary of the Company s stock option activity for all equity incentive plans for the nine months ended September 30, 2010 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, 2009	5,890	$ 44.96		
Granted	1,059	43.27		
Exercised	(773)	29.15		
Cancelled	(336)	51.12		
Outstanding at September 30, 2010	5,840	$ 46.39	4.5	$ 32,203
Exercisable at September 30, 2010	3,813	$ 46.21	3.8	$ 22,571

Restricted Stock and Deferred Issuance Restricted Stock

A summary of the Company s restricted stock and deferred issuance restricted stock award activity during the nine months ended September 30, 2010 is as follows (in thousands, except price per share data):

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2009	247	$ 55.19
Granted	4	46.82
Vested and exercised	(81)	54.96

Forfeited	(13)		56.17
Outstanding at September 30, 2010	157	$	55.00

Performance Stock Awards

In February 2010, the Company transitioned from its historical practice of granting certain senior Company employees restricted stock awards with time-based vesting provisions only, to granting these employees the right to receive a designated number of shares of common stock (the Performance Stock Awards) based on the achievement of specific performance levels related to the Company s 2010 revenues, earnings per share and return on invested

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capital (collectively, the Performance Stock Award Criteria). The Performance Stock Awards were granted under the Company s 2003 Incentive Award Plan and are intended to qualify as performance-based compensation under Section 162(m) of the Internal Revenue Code, as amended.

Pursuant to the terms of the applicable Performance Stock Award agreement, each recipient may receive between zero and up to 150% of the target number of shares of Company stock originally granted based on actual performance as measured against the Performance Stock Award Criteria. If the Company fails to achieve an identified threshold level of performance for any of the Performance Stock Award Criteria, no Company stock will be awarded for that Performance Stock Award Criteria.

In the first quarter of 2011, the Compensation Committee of the Company s Board of Directors will determine the number of shares of Company stock, if any, that will be issued to award recipients based on actual performance. Shares of Company stock to be issued in the first quarter of 2011, pursuant to the terms of the applicable Performance Stock Award agreements, will vest one-third on the date of issuance, one-third on the first anniversary of the date of issuance and one-third on the second anniversary of the date of issuance, so long as the award recipient is employed by the Company on each such date.

A summary of the Company s Performance Stock Award activity for the nine months ended September 30, 2010 is as follows (in thousands, except price per share data):

	Number of Shares	Maximum Shares Eligible to Receive	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2009			$
Awarded	70	104	42.66
Forfeited	(5)	(7)	42.66
Outstanding at September 30, 2010	65	97	$ 42.66

Stock Repurchase Programs

In August 2008, the Company s Board of Directors authorized the repurchase of up to $250.0 million of the Company s common stock over the two year period following adoption of the program, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. The Company completed the program in August 2009, repurchasing and retiring approximately 5,989,000 shares since the program s inception at an average price of $41.72, or approximately $249.8 million in total.

In February 2010, the Company s Board of Directors authorized the repurchase of up to $100.0 million of the Company s common stock until December 31, 2010, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the three months ended September 30, 2010, the Company repurchased and retired approximately 776,300 shares under this program at an average price of $46.09 per share, or approximately $35.8 million in total. As of September 30, 2010, the Company has repurchased approximately 1,920,000 shares under this program since its inception at an average price of $45.87, or approximately $88.1 million in total.

Note 12 Derivative Financial Instruments

In 2009, the Company began entering into foreign currency forward contracts to reduce its exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These forward contracts generally had a maturity of approximately 30 days and were not designated as hedges. Accordingly, these instruments were marked to market at each balance sheet date with changes in fair value recognized in earnings under the caption Other income (expense), net. The Company did not enter into any foreign currency forward contracts during the quarter ended September 30, 2010.

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The following table reflects the effect of these derivative instruments on the consolidated statements of income for the three and nine month periods ended September 30, 2010 and 2009 (in thousands):

Derivatives Not Designated as Hedging Instruments Under ASC 815-10:	Location of Loss Recognized in Income	Three Months Ended September 30,		Nine Months Ended September 30,	
		2010	2009	2010	2009
Foreign currency forward contracts	Other income (expense), net	$ 27	$	$	$ (635)

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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, p intends, estimates, could, should, would, continue, seeks or anticipates, or other similar words, includin 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, 2010 unaudited consolidated interim financial statements and related notes included elsewhere in this quarterly report and with our audited consolidated financial statements and related notes for the year ended December 31, 2009 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations section contained in our Annual Report on Form 10-K for the year ended December 31, 2009. 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, 2009. Some totals included in the Management s Discussion and Analysis of Financial Condition and Results of Operations section and elsewhere in this Quarterly Report on Form 10-Q may not foot due to rounding.

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid tests, or NATs, used primarily to diagnose human diseases and screen donated human blood. NATs are designed to detect diseases more rapidly and/or accurately than older tests, and are among the fastest-growing categories of the *in vitro* diagnostics industry.

We market a broad portfolio of products to detect infectious microorganisms, including those causing sexually transmitted diseases, or STDs, tuberculosis, strep throat and other infections. Our leading clinical diagnostics products include our APTIMA family of assays that are used to detect the common STDs chlamydia and gonorrhea.

In 2009, we expanded our portfolio of products with acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel Life Sciences plc, or Tepnel, offers diagnostic products to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse, Inc., or Prodesse, added a portfolio of real-time polymerase chain reaction, or PCR, products for detecting influenza and other infectious organisms.

In blood screening, we developed and manufacture the PROCLEIX assays, which are used to detect human immunodeficiency virus (type 1), or HIV, the hepatitis C virus, or HCV, the hepatitis B virus and the West Nile virus in donated human blood. Our blood screening products are marketed worldwide by Novartis Vaccines and Diagnostics, Inc., or Novartis. We were awarded the 2004 National Medal of Technology, the nation s highest honor for technological innovation, in recognition of our pioneering work in developing NATs to safeguard the nation s blood supply.

Several of our current and future molecular tests can be performed on our TIGRIS instrument, a fully automated, high-throughput NAT system for diagnostics and blood screening. We are building on the success of our TIGRIS instrument system by developing our next-generation PANTHER instrument system, which is designed to be a versatile, fully automated NAT system for low- to mid-volume laboratories.

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In addition to PANTHER, our development pipeline includes NATs to detect:

human papillomavirus, or HPV, which causes cervical cancer;

gene-based markers for prostate cancer;

Trichomonas, a common parasite that causes a prevalent STD;

certain respiratory infections; and

human leukocyte antigens, or HLAs, which are used to determine transplant compatibility.

Recent Events

Financial Results

Product sales for the third quarter of 2010 were $128.3 million, compared to $119.0 million in the same period of the prior year, an increase of 8%. Total revenues for the third quarter of 2010 were $132.6 million, compared to $122.7 million in the same period of the prior year, an increase of 8%. Net income for the third quarter of 2010 was $27.4 million ($0.56 per diluted share), compared to $22.2 million ($0.44 per diluted share) in the same period of the prior year, an increase of 23%.

Product sales for the first nine months of 2010 were $391.6 million, compared to $348.3 million in the same period of the prior year, an increase of 12%. Total revenues for the first nine months of 2010 were $406.6 million, compared to $359.4 million in the same period of the prior year, an increase of 13%. Net income for the first nine months of 2010 was $79.7 million ($1.61 per diluted share), compared to $67.8 million ($1.31 per diluted share) in the same period of the prior year, an increase of 18%.

Our total revenues, net income and fully diluted earnings per share during the first nine months of 2010 included the results of operations of both Tepnel and Prodesse. In contrast, our total revenues, net income and fully diluted earnings per share during the first nine months of 2009 only included the results of operations of Tepnel from the date of acquisition in April 2009, as well as $8.2 million of additional one-time revenue associated with the renegotiation of our collaboration agreement with Novartis, which we recognized in the first quarter of 2009.

Collaboration with and Investment in Pacific Biosciences of California, Inc.

In June 2010, we entered into a collaboration agreement with Pacific Biosciences of California, Inc., or Pacific Biosciences, regarding the research and development of instruments integrating our sample preparation technologies and Pacific Biosciences single-molecule deoxyribonucleic acid, or DNA, sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the initial term of the collaboration will end on the earlier of December 15, 2012 or six months after Pacific Biosciences demonstrates the proof of concept of its V2 single-molecule DNA sequencing system. Concurrently with the execution of the collaboration agreement, we also purchased $50.0 million of Pacific Biosciences Series F preferred stock, as a participant in Pacific Biosciences Series F preferred stock round of financing that raised a total of approximately $109.0 million. In October 2010, Pacific Biosciences completed an initial public offering of its common stock. As a result of the initial public offering, our preferred stock was converted into common stock.

Stock Repurchase Program

In February 2010, our Board of Directors authorized the repurchase of up to $100.0 million of our common stock until December 31, 2010, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the three months ended September 30, 2010, we repurchased and retired approximately 776,300 shares under this program at an average price of $46.09 per share, or approximately $35.8 million in total. As of September 30, 2010, we have repurchased approximately 1,920,000 shares under this program since its inception at an average price of $45.87, or approximately $88.1 million in total.

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Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our unaudited interim consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these interim consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectability of accounts receivable, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; liabilities associated with employee benefit costs and contingent consideration; inventories; and goodwill and long-lived assets, including patent costs, capitalized software, acquired intangible assets and licenses and manufacturing access fees. We base our estimates on historical experience and on various other assumptions that we believe are 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 third quarter of 2010 to the items that we disclosed as our critical accounting policies and estimates in the Management s Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the year ended December 31, 2009.

Pending Adoption of Recent Accounting Pronouncements

Accounting Standards Update 2010-06

In January 2010, the Financial Accounting Standards Board, or FASB, amended Accounting Standards Codification, or ASC, Topic 820, Fair Value Measurements and Disclosures, to require reporting entities to make new disclosures about recurring and nonrecurring fair value measurements, including significant transfers into and out of Level 1 and Level 2 fair value measurements and information about purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. Except for the detailed Level 3 roll forward disclosures, the guidance was effective January 1, 2010. The new disclosures about purchases, sales, issuances, and settlements in the roll forward activity for Level 3 fair value measurements are effective for us as of January 1, 2011. Early adoption is permitted. The adoption of this standard will not affect our financial position or results of operations.

Accounting Standards Update 2010-17

In March 2010, the FASB ratified the final consensus that offers an alternative method of revenue recognition for milestone payments. The guidance states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance will be effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted, provided that the revised guidance is applied retrospectively to the beginning of the year of adoption. The guidance may be applied retrospectively or prospectively for milestones achieved after the adoption date. We are currently evaluating early prospective adoption and determining the effects, if any, the adoption of this guidance will have on our consolidated financial statements.

Accounting Standards Update 2009-13

In September 2009, the FASB revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for our fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We are currently evaluating early prospective adoption and determining the effects, if any, the adoption of this guidance will have on our consolidated financial statements.

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Results of Operations

Product Sales

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	$ Change	% Change	2010	2009	$ Change	% Change
Clinical diagnostics	$ 74.9	$ 69.6	$ 5.3	8%	$ 225.7	$ 196.6	$ 29.1	15%
Blood screening	50.3	45.4	4.9	11%	155.5	144.1	11.4	8%
Research products and services	3.1	4.0	(0.9)	(22)%	10.4	7.6	2.8	37%
Total product sales	$ 128.3	$ 119.0	$ 9.3	8%	$ 391.6	$ 348.3	$ 43.3	12%
As a percent of total revenues	97%	97%			96%	97%		

Our primary source of revenue comes from product sales, which consist primarily of the sale of clinical diagnostics and blood screening products. Our clinical diagnostic product sales consist primarily of the sale of our women s health, virology, other infectious disease, transplant diagnostics, and prostate oncology products. The principal customers for our clinical diagnostics products include reference laboratories, public health institutions and hospitals. The blood screening assays and instruments we manufacture are marketed and distributed 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 end users, 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 8% for the three months ended September 30, 2010 as compared to the same period of the prior year. The increase was primarily attributed to higher APTIMA assay sales, higher blood screening revenues, as well as additional product sales resulting from our acquisition of Prodesse in October 2009. Product sales increased 12% for the nine months ended September 30, 2010 as compared to the same period of the prior year. The increase was primarily attributed to higher APTIMA assay sales, higher blood screening revenues, an additional three months of sales resulting from our acquisition of Tepnel in April 2009, and an additional nine months of sales resulting from our acquisition of Prodesse in October 2009.

Clinical Diagnostic Product Sales

The increase in clinical diagnostic product sales, including assay, instrument and ancillary sales, in the three months ended September 30, 2010 as compared to the same period in the prior year was primarily attributed to volume gains in our APTIMA product line, as well as the addition of product sales resulting from our acquisition of Prodesse in October 2009. The increase in clinical diagnostic product sales, including assay, instrument and ancillary sales, for the nine months ended September 30, 2010 as compared to the same period in the prior year was primarily attributed to volume gains in our APTIMA product line, as well as the addition of product sales resulting from our acquisitions of Tepnel in April 2009 and Prodesse in October 2009.

In both the three and nine month periods ended September 30, 2010, clinical diagnostic product sales benefited from customer conversion from our non-amplified PACE test to our amplified APTIMA test. 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.

Clinical diagnostic product sales were negatively affected during the three months ended September 30, 2010 as compared to the same period of 2009 by an estimated exchange rate impact of $0.5 million due to a stronger U.S. dollar. Clinical diagnostic product sales were positively affected during the nine months ended September 30, 2010 as

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compared to the same period of 2009 by an estimated exchange rate impact of $0.5 million, primarily due to a weaker U.S. dollar against the Canadian dollar.

Blood Screening Product Sales

The overall increase in blood screening product sales, including assay, instrument and ancillary sales, in the three and nine month periods ended September 30, 2010, as compared to the same periods in the prior year was primarily attributed to an increase in underlying blood screening product sales resulting primarily from an increase in blood screening shipments, the contractual increase in the net percentage share of revenues we receive from Novartis, as well as an increase in the sale of blood screening-related instrumentation. In addition, the nine month period ended September 30, 2009 included $8.2 million of one-time revenue recognized during the first quarter of 2009 as a result of the renegotiation of our collaboration agreement with Novartis.

Blood screening product sales were negatively affected during the three months ended September 30, 2010 as compared to the same period of 2009 by an estimated exchange rate impact of $1.0 million due to a stronger U.S. dollar, primarily versus the Euro. Blood screening product sales were positively affected during the nine months ended September 30, 2010 as compared to the same period of 2009 by an estimated exchange rate impact of $1.0 million due to a weaker U.S. dollar, primarily versus the Australian dollar.

Research Products and Services

As a result of our acquisition of Tepnel in April 2009, we have a new category of product sales, which we refer to as Research products and services. These sales represent outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies. These sales totaled $3.1 million and $10.4 million during the three and nine months ended September 30, 2010, respectively, as compared to $4.0 million and $7.6 million, respectively, for the three and nine months ended September 30, 2009. The decrease for the three months ended September 30, 2010 as compared to the same period of the prior year was due to revenue included in the prior period related to our Biokits food safety testing business, which we sold in December 2009. The increase for the nine months ended September 30, 2010 as compared to the same period of the prior year was attributed to the inclusion of an additional quarter of research products and services revenues that were not present in the prior year period due to our acquisition of Tepnel in April 2009.

Collaborative Research Revenue

(Dollars in millions)	**Three Months Ended September 30,**				**Nine Months Ended September 30,**			
	2010	**2009**	**$ Change**	**% Change**	**2010**	**2009**	**$ Change**	**% Change**
Collaborative research revenue	$ 3.4	$ 2.0	$ 1.4	70%	$ 10.8	$ 5.9	$ 4.9	83%
As a percent of total revenues	3%	2%			3%	2%		

We recognize collaborative research revenue over the term of various collaboration agreements, as negotiated monthly contracted amounts are earned, in relative proportion to the performance required under the contracts, or as reimbursable costs are incurred related to those agreements. 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 U.S. Food and Drug Administration, or 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 our 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 70% and 83% during the three and nine months ended September 30, 2010 compared to the same periods of 2009, primarily due to reimbursements from Novartis for shared development expenses, primarily attributable to the development of the PANTHER instrument and product enhancements for use in the blood screening market.

Collaborative research revenue tends to fluctuate based on the type and amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative research revenue, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate additional collaborative research revenue 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.

Royalty and License Revenue

(Dollars in millions)	**Three Months Ended September 30,**				**Nine Months Ended September 30,**			
	2010	**2009**	**$ Change**	**% Change**	**2010**	**2009**	**$ Change**	**% Change**
Royalty and license revenue	$ 0.8	$ 1.8	$ (1.0)	(56)%	$ 4.2	$ 5.3	$ (1.1)	(21)%
As a percent of total revenues	1%	1%			1%	1%		

We recognize revenue for royalties due to us under license agreements with third parties upon the manufacture, sale or use of our products or technologies. 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 decreased 56% and 21% during the three and nine months ended September 30, 2010, respectively, as compared to the same periods of 2009. In each case, the decrease was primarily a result of lower royalties received from Novartis associated with collaboration royalties from the plasma testing market.

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 commercialize our technologies.

Cost of Product Sales

(Dollars in millions)	**Three Months Ended September 30,**				**Nine Months Ended September 30,**			
	2010	**2009**	**$ Change**	**% Change**	**2010**	**2009**	**$ Change**	**% Change**
Cost of product sales	$ 42.1	$ 36.3	$ 5.8	16%	$129.1	$107.9	$ 21.2	20%
Gross profit margin as a percent of product sales	67%	69%			67%	69%		

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. Cost of product sales excludes the amortization of acquisition-related intangibles.

In addition, we manufacture significant quantities of materials, development lots, and clinical trial lots of product prior to receiving approval from the FDA 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 is capitalized to inventory and classified as cost of product sales upon shipment.

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Cost of product sales increased 16% during the three months ended September 30, 2010, as compared to the same period of 2009. The increase was primarily due to additional cost of product sales as a result of our acquisition of Prodesse and increases attributed to increased instrumentation, APTIMA, and blood screening product shipments. These increased costs were partially offset by favorable manufacturing variances related to changes in production volumes.

Cost of product sales increased 20% during the nine months ended September 30, 2010 as compared to the same period of 2009. The increase was primarily due to additional cost of product sales as a result of our acquisitions of Tepnel and Prodesse and increases attributed to increased instrumentation, APTIMA, and blood screening product shipments. These increased costs were partially offset by a decrease in scrap expense and favorable manufacturing variances related to changes in production volumes.

Our gross profit margin as a percentage of product sales decreased to 67% for both the three and nine months ended September 30, 2010, a decrease of 2% as compared to the same periods of 2009. In each case, the decreases were primarily attributed to increased sales of lower margin instrumentation and lower overall gross margin percentages on our blood screening and acquired Tepnel businesses that were caused in part by unfavorable foreign exchange rates. These decreases were partially offset by favorable manufacturing variances related to changes in production volumes.

Cost of 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 is 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.

A portion of our blood screening revenues is attributable to sales of TIGRIS instruments to Novartis, which totaled $14.0 million and $8.8 million during the first nine months of 2010 and 2009, respectively. Under our collaboration agreement with Novartis, we sell TIGRIS instruments to Novartis at prices that approximate cost and share in profits of end-user sales in the United States. These instrument sales, therefore, negatively impact our gross margin percentage during the periods in which they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

Acquisition-related Intangible Amortization

(Dollars in millions)	**Three Months Ended September 30,**				**Nine Months Ended September 30,**			
	2010	**2009**	**$ Change**	**% Change**	**2010**	**2009**	**$ Change**	**% Change**
Acquisition-related intangible amortization	$ 2.2	$ 1.1	$ 1.1	100%	$ 6.6	$ 2.3	$ 4.3	187%
As a percent of total revenues	2%	1%			2%	1%		

Amortization expense related to our acquired intangible assets was $2.2 million and $6.6 million during the three and nine month periods ended September 30, 2010, respectively, as compared to $1.1 million and $2.3 million, respectively, during the three and nine month periods ended September 30, 2009. These increases were attributable to our October 2009 acquisition of Prodesse and its related intangible assets, which were not included in our intangible asset amortization expense for the three and nine month periods ended September 30, 2009. In addition, our acquisition-related intangible amortization expense for the nine months ended September 30, 2010 as compared to the same period of the prior year also included an additional quarter of amortization expense related to Tepnel s acquired intangible assets. Our acquired intangible assets are amortized using the straight-line method over their estimated useful lives, which range from 10 to 20 years. For details on the intangible assets acquired as part of our acquisitions of Tepnel and Prodesse, please refer to Note 2 Business Combinations, of the Notes to the Consolidated Financial Statements included elsewhere in this report.

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Research and Development

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	$ Change	% Change	2010	2009	$ Change	% Change
Research and development	$ 27.4	$ 27.5	$ (0.1)	0%	$ 84.2	$ 78.5	$ 5.7	7%
As a percent of total revenues	21%	22%			21%	22%		

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 our research and development activities. The additional costs include development and validation activities for our HPV, PCA3 and Trichomonas assays, development of our PANTHER instrument, assay integration and validation activities for PANTHER, development and validation of assays for blood screening and ongoing research and early stage development activities. Although total R&D expenditures may increase over time, we expect that our R&D expenses as a percentage of total revenues will decline in future years.

R&D expenses during the three months ended September 30, 2010 were comparable to the same period in 2009. R&D expenses increased by 7% during the nine months ended September 30, 2010 as compared to the same period in 2009. The increase was related to our acquired Prodesse business, partially offset by a decline in development expenses due to the wind-down of clinical trials for our HPV, PCA3, and Trichomonas assays.

Marketing and Sales

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	$ Change	% Change	2010	2009	$ Change	% Change
Marketing and sales	$ 13.9	$ 13.5	$ 0.4	3%	$ 44.5	$ 38.5	$ 6.0	16%
As a percent of total revenues	10%	11%			11%	11%		

Our marketing and sales expenses include salaries and other personnel-related expenses, promotional expenses and fees for outside services.

Marketing and sales expenses increased 3% and 16% during the three and nine months ended September 30, 2010, respectively, as compared to the same periods in 2009. In each case, the increase was primarily attributed to an increase in salaries, personnel-related expenses, and marketing activities due to our continued investment in international expansion, primarily in Western Europe, and our acquisition of Prodesse in October 2009.

General and Administrative

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	$ Change	% Change	2010	2009	$ Change	% Change
General and administrative	$ 11.5	$ 15.2	$ (3.7)	(24)%	$ 41.2	$ 46.9	$ (5.7)	(12)%
As a percent of total revenues	9%	12%			10%	13%		

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 decreased 24% and 12% during the three and nine months ended September 30, 2010, respectively, as compared to the same periods of 2009. In each case, the decrease was primarily attributable to the receipt in August 2010 of a $2.9 million arbitration award for attorneys fees and costs related to an arbitration proceeding with Digene Corporation (now Qiagen Gaithersburg, Inc.), and lower G&A costs associated with our acquired Tepnel businesses.

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This was partially offset by an increase in legal fees relating to the litigation with Becton Dickinson and Company, or BD, and an increase in expenses related to the consolidation of our UK operations.

Other Income (Expense)

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	$ Change	% Change	2010	2009	$ Change	% Change
Investment and interest income	$ 3.2	$ 4.7	$ (1.5)	(32)%	$ 10.4	$ 19.7	$ (9.3)	(47)%
Interest expense	(0.6)	(0.6)		0%	(1.7)	(1.5)	(0.2)	13%
Gain on contingent consideration	1.5		1.5	N/M	7.6		7.6	N/M
Other income (expense), net	0.3	0.2	0.1	50%	(0.1)	(0.8)	0.7	(88)%
Total other income, net	$ 4.4	$ 4.3	$ 0.1	2%	$ 16.2	$ 17.4	$ (1.2)	(7)%

The decreases in investment and interest income during the three and nine months ended September 30, 2010, as compared to the same periods of 2009, were primarily attributed to lower net realized gains on sales of marketable securities, as well as decreased interest income due to lower investment balances in the current year periods as a result of the liquidation of investments to fund our recent acquisitions and higher purchase premium amortizations arising from increased market demand for tax-advantaged municipal bonds. Interest expense attributable to borrowings under our credit facility with Bank of America during the nine months ended September 30, 2010 increased as compared to the prior year period due to higher average monthly fees based on the London Interbank Offered Rate, or LIBOR. The net increase in other income and the net decrease in other expense during the three and nine months ended September 30, 2010, respectively, as compared to the same periods of 2009 were primarily attributable to exchange rate impacts.

We recorded non-cash gains of $1.5 million and $7.6 million during the three and nine months ended September 30, 2010, respectively, as a result of a reduction in the fair value of the contingent consideration liability related to our acquisition of Prodesse. These reductions were primarily associated with lower anticipated payouts for the related milestones. In July 2010, we received FDA clearance of our ProFAST + assay, thereby satisfying one of the acquisition-related milestones and triggering a $10.0 million payment to former Prodesse securityholders. Future milestone payments, if any, will occur between the first quarter of 2011 and the second quarter of 2012.

Income Tax Expense

(Dollars in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	$ Change	% Change	2010	2009	$ Change	% Change
Income tax expense	$ 12.4	$ 11.1	$ 1.3	12%	$ 37.5	$ 34.9	$ 2.6	7%
As a percent of income before tax	31%	33%			32%	34%		

The decreases in our effective tax rate for the three and nine months ended September 30, 2010 compared to the same periods in the prior year were largely due to the expiration of statute of limitations for past tax returns, the adjustments to contingent consideration in the current year periods that are generally not taxable, and a statutory increase in U.S. domestic manufacturing tax benefits, offset by the expiration of the federal research credit which has not been reinstated in the current year, and lower tax-advantaged interest income.

Liquidity and Capital Resources

	September 30, 2010	December 31, 2009
	(In thousands)	
Cash, cash equivalents and current marketable securities	$422,563	$ 485,606
Working capital	283,816	333,560
Current ratio	2:1	2:1

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Our working capital at September 30, 2010 decreased $49.7 million from December 31, 2009 primarily due to the use of cash and investments to make our $50.0 million investment in Pacific Biosciences and to repurchase shares under our current stock repurchase program, partially offset by cash generated from operations.

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 marketable securities include treasury securities, tax advantaged municipal securities and Federal Deposit Insurance Corporation, or FDIC, insured corporate bonds with a minimum Moody s credit rating of A3 or a Standard & Poor s credit rating of A-. As of September 30, 2010, we did not hold auction rate securities and have never held any such 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, 2010, our portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody s.

	Nine Months Ended September 30,		
	2010	2009	$ Change
	(In thousands)		
Cash provided by (used in):			
Operating activities	$125,814	$106,726	$ 19,088
Investing activities	15,606	(81,442)	97,048
Financing activities	(73,741)	69,827	(143,568)
Purchases of property, plant and equipment (included in investing activities above)	(22,090)	(22,284)	194

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. Additionally, our liquidity was enhanced in 2009 by our credit facility with Bank of America, described in Note 8 Borrowings, of the Notes to the Consolidated Financial Statements included elsewhere in this report. 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. In addition, we may use cash for strategic purchases which may include the acquisition of businesses and/or technologies complementary to our business. Certain R&D costs may be funded under collaboration agreements with our collaboration partners.

Operating activities provided net cash of $125.8 million during the first nine months of 2010, primarily from net income of $79.7 million and net non-cash charges of $46.3 million. Non-cash charges primarily consisted of depreciation of $20.9 million, stock based compensation expense of $18.5 million and amortization of intangibles of $13.2 million.

Investing activities provided net cash of $15.6 million during the first nine months of 2010. We received $92.9 million in net proceeds from the sale and maturities of marketable securities in the first nine months of 2010. This was offset by a $50.0 million investment in Pacific Biosciences and purchases of property, plant and equipment of $22.1 million.

Net cash used in financing activities during the first nine months of 2010 was $73.7 million, primarily driven by $88.1 million used to repurchase and retire approximately 1,920,000 shares of our common stock under our current stock repurchase program and a $10.0 million payment made to former Prodesse securityholders for achievement of an acquisition-related milestone, partially offset by $24.7 million in proceeds from the issuance of our common stock under stock option and employee stock purchase programs.

We believe that our available cash balances, anticipated cash flows from operations, proceeds from stock option exercises and borrowings under our credit facility will be sufficient to satisfy our operating needs for the foreseeable

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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. Because our current credit facility is secured by our marketable securities, any significant needs for cash may cause us to liquidate some or all of our marketable securities resulting in the need to partially or completely pay down our credit facility.

Contractual Obligations and Commercial Commitments

Our contractual obligations due as of September 30, 2010 were as follows (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Material purchase commitments[1]	$ 27,431	$ 17,862	$ 4,418	$ 4,292	$ 859
Operating leases[2]	25,104	1,791	4,440	3,102	15,771
Collaborative commitments[3]	3,615	100	1,927	794	794
Minimum royalty commitments[4]	15,573	328	3,170	3,840	8,235
Deferred employee compensation[5]	3,692	672	1,562	892	566
Capital leases[6]	464	237	198	29	
Contingent consideration[7]	399	188	211		
Fixed-rate debt, including accrued interest[8]	1,127	364	288	254	221
Credit facility, including accrued interest[9]	240,870	240,870			
Total[10]	$ 318,275	$ 262,412	$ 16,214	$ 13,203	$ 26,446

(1) Amounts represent our minimum purchase commitments for instruments and raw materials from key vendors. Of the $27.4 million total, $7.0 million is expected to be used to purchase TIGRIS instruments, of which we anticipate that approximately $5.4 million of

instruments will be sold to Novartis. Not included in the $27.4 million is $3.4 million expected to be used to purchase production PANTHER instruments, and associated tooling, pursuant to our development agreement with Stratec Biomedical Systems AG, or Stratec, as well as potential minimum purchase commitments under our supply agreement with Stratec. Our obligations under the supply agreement are contingent upon successful completion of all activities under our development agreement with Stratec.

(2) Reflects obligations for facilities and vehicles under operating leases in place as of September 30, 2010. Future minimum lease payments are included in the

table above.

(3) In addition to the minimum payments due under our collaborative agreements included in the table above, we may be required to pay up to $11.2 million in milestone payments, plus royalties on net sales of any products using specified technology. We may also be required to pay up to $1.9 million in future development costs in the form of milestone payments.

(4) Amounts represent our minimum royalties due on the net sales of products incorporating licensed technology and subject to a minimum annual royalty payment. During the three and nine months ended September 30, 2010, we recorded $2.3 million and $7.1 million,

respectively, in royalty costs related to our various license agreements.

(5) The $3.7 million represents deferred compensation plan liabilities for in-service distributions. Our total deferred compensation plan liability as of September 30, 2010 was $5.8 million, which includes the $3.7 million included in the table above and $2.1 million due to employees upon retirement. We have excluded the amount payable

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upon employee retirement from the table above as we cannot reasonably predict when such retirement events may occur.

(6) Reflects obligations on capital leases in place as of September 30, 2010. Interest amounts were not material; therefore, capital lease obligations are shown net of interest expense in the table above.

(7) Represents the aggregate fair value of the payments we may be obligated to make to former Prodesse securityholders. This amount is reflected in our consolidated balance sheets under the captions Other accrued expenses and Other long-term liabilities. In July 2010, we received FDA clearance of our ProFAST + assay, thereby satisfying one of the acquisition-related milestones and triggering a $10.0 million

payment to former Prodesse securityholders. Future milestone payments, if any, will occur between the first quarter of 2011 and the second quarter of 2012.

(8) Reflects the total outstanding principal amount of £0.5 million, or $0.8 million based on the exchange rate of £1 to $1.58 as of the balance sheet date, of a pre-existing fixed-rate term loan which we acquired in connection with our acquisition of Tepnel. Interest payable on this outstanding amount included in the table above has been estimated based on the interest rate payable at September 30, 2010, which was approximately 6.6%.

(9) As of September 30, 2010, the total principal amount outstanding under our revolving credit facility with Bank of America was $240.0 million. The term of this

credit facility is due to expire in February 2011. Interest payable on this outstanding amount included in the table above has been estimated based on the interest rate payable at September 30, 2010, which was approximately 0.86%. At our option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America s prime rate and (iii) LIBOR plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by us. In addition, we are required to pay interest and fees on the undrawn sub-limit of up to $10.0 million for the issuance of letters of credit under the credit facility, which has also been estimated for the remaining term of the credit facility

based on the fixed-rate of 0.25% at September 30, 2010.

(10) Does not include amounts relating to our obligations under our collaboration with Novartis, pursuant to which both parties have obligations to each other. Under our collaboration agreement with Novartis, 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 $8.4 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.

Off-Balance Sheet Arrangements

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.

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Available Information

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our investment portfolio and the amount of interest payable on our senior secured revolving credit facility with Bank of America. As of September 30, 2010, the total principal amount outstanding under the revolving credit facility was $240.0 million. At our option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America s prime rate and (iii) LIBOR plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by us. We do not believe that we are exposed to significant interest rate risk with respect to our credit facility based on our option to select the rate at which interest accrues under the credit facility, the short-term nature of the borrowings and our ability to pay off the outstanding balance in a timely manner if the applicable interest rate under the credit facility increases above the current interest rate yields on our investment portfolio. A 100 basis point increase or decrease in interest rates would increase or decrease our interest expense by approximately $2.4 million on an annual basis.

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 investment grade securities with an average portfolio maturity of no more than three years. A 25 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately $1.8 million. While changes in interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our consolidated statements of income until the investment is sold or if a reduction in fair value is determined to be other-than-temporary.

Foreign Currency Exchange Risk

Although the majority of our revenue is realized in U.S. 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. We translate the financial statements of our non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates in intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders equity under the caption Accumulated other comprehensive income. These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Under our collaboration agreement with Novartis, a growing portion of blood screening product sales is from western European countries. As a result, our international blood screening product sales are affected by changes in the foreign currency exchange rates of those countries where Novartis business is conducted in Euros or other local currencies. Based on international blood screening product sales during the first nine months of 2010, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.0 million annually. Similarly, a 10% movement of currency exchange rates would result in a clinical diagnostic product sales increase or decrease of approximately $4.7 million annually. A 10% movement of currency exchange rates would result in a research products and services sales increase or decrease of approximately $1.4 million annually. The majority of our collaborative research revenues and royalty and license revenues are denominated in U.S. dollars and, as such, are not subject to exchange rate exposure. Our exposure for both blood

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screening and clinical diagnostic product sales is primarily in the U.S. dollar versus the Euro, British pound, Australian dollar and Canadian dollar.

Our total payables denominated in foreign currencies as of September 30, 2010 were not material. Our gross trade receivables by currency as of September 30, 2010 reflected in U.S. dollar equivalents were as follows (in thousands):

U.S. dollar	$ 47,585
Euro	5,098
British pound	2,777
Canadian dollar	1,818
Czech koruna	226
Danish krone	99
Swiss franc	16
Norwegian kroner	3
Total gross trade accounts receivable	$ 57,622

In order to reduce the effect of foreign currency fluctuations, we periodically utilize foreign currency forward contracts, or forward contracts, to hedge certain foreign currency transaction exposures. Specifically, we enter into forward contracts with a maturity of approximately 30 days to hedge against the foreign exchange exposure created by certain balances that are denominated in a currency other than the principal reporting currency of the entity recording the transaction. The forward contracts do not qualify for hedge accounting and, accordingly, all of these instruments are marked to market at each balance sheet date by a charge to earnings. The gains and losses on the forward contracts are meant to mitigate the gains and losses on these outstanding foreign currency transactions. We believe that these forward contracts do not subject us to undue risk due to foreign exchange movements because gains and losses on these contracts are generally offset by losses and gains on the underlying assets and liabilities. We do not use derivatives for trading or speculative purposes.

We did not enter into any foreign currency forward contracts during the quarter ended September 30, 2010.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures and internal controls that are designed to ensure that information required to be disclosed in our current and periodic reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures and internal controls, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In addition, the design of any system of controls is also 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.

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

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Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2010.

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, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As of the date of this report, we have not completed our assessment of Prodesse s internal control over financial reporting. As a result, we have excluded Prodesse from the evaluation of our internal control over financial reporting contained in this report.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 10 Contingencies, of the Notes to the Consolidated Financial Statements included elsewhere in 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

Set forth below and elsewhere in this Quarterly Report on Form 10-Q, and in other documents we file with the SEC, are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones we face. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition. 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, 2009.

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, including fluctuations in demand for blood screening tests from our blood screening collaboration partner Novartis, the timing of acquisitions, the execution of customer contracts, the receipt of milestone payments, or the failure to achieve and receive the same, and the initiation or termination of corporate collaboration agreements. In addition, a significant portion of our costs can also 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, certain of our products have a relatively limited sales history, which limits our ability to accurately project future sales, prices and related sales cycles. 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

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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. In addition, our respiratory infectious disease product line is subject to significant seasonal fluctuations. 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.

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. Although these effects are difficult to quantify, we believe that relative to our expectations we have experienced modest declines in product sales growth rates in recent periods, due in part to current macroeconomic conditions and pressures on healthcare utilization. A continued weakening of the global and domestic economies, 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 38% of our total revenues during the first nine months of 2010 and 40% of our total revenues for 2009. In January 2009, we extended the term of our blood screening collaboration with Novartis to June 30, 2025, subject to earlier termination under certain limited circumstances specified in the collaboration agreement. In addition, we supply our transcription-mediated amplification, or TMA, assay for the qualitative detection of HCV and analyte specific reagents, or ASRs, for the quantitative detection of HCV to Siemens Healthcare Diagnostics, Inc., or Siemens, pursuant to a collaboration agreement.

We rely upon bioMérieux S.A., or bioMérieux, for distribution of certain of our products in most of Europe and Australia, Fujirebio, Inc., or Fujirebio, 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 agreements with Fujirebio and bioMérieux expire in December 2012 and May 2012, respectively, although each agreement may terminate earlier under certain circumstances.

If any of our distribution or marketing agreements is terminated, particularly our collaboration agreement with Novartis, 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 blood screening collaboration with Novartis would have a material adverse effect on our business.*

We rely, to a significant extent, on our corporate collaborators for funding development for and marketing certain of our products. In addition, we expect to rely on our corporate collaborators for the commercialization of certain products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to

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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 Corporation, or 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.

In June 2010, we entered into a collaboration agreement with Pacific Biosciences regarding the research and development of instruments integrating our sample preparation technologies and Pacific Biosciences single-molecule DNA sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the initial term of the collaboration will end on the earlier of December 15, 2012 and six months after Pacific Biosciences demonstrates the proof of concept of its V2 single-molecule DNA sequencing system.

The continuation of any of our collaboration agreements depends on their periodic renewal by us and our collaborators. For example, in January 2009 we extended the term of our blood screening collaboration with Novartis to June 30, 2025, subject to earlier termination under certain limited circumstances specified in the collaboration agreement. The collaboration was previously scheduled to expire by its terms in 2013.

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 effect on our business or operating results.

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, and acquired companies or technologies could be difficult to integrate and could disrupt our business.

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 in 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 may also 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.

In April 2009, we completed our acquisition of Tepnel, which we believe provides us with access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerates our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe. In addition, in October 2009 we acquired Prodesse, which we believe supports our strategic focus on commercializing differentiated molecular tests for infectious diseases. Our beliefs regarding the merits of these acquisitions are based upon numerous assumptions that are subject to risks and uncertainties that could deviate materially from our estimates, and could adversely affect our operating results.

Managing the acquisitions of Tepnel and Prodesse, as well as any other future acquisitions, will entail numerous operational and financial risks, including:

- the anticipated financial performance and estimated cost savings and other synergies as a result of the acquisitions may not materialize;

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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;

the risk of entering new markets; and

integrating, or completing the development and application of, any acquired technologies and personnel with diverse business and cultural backgrounds, which could disrupt our business and divert our management s time and attention.

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 at all, or on terms that are favorable to us.

Our future success will depend in part upon our ability to enhance existing products and to develop, introduce and commercialize 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. For example, our failure to successfully develop and commercialize our development-stage PANTHER instrument system on a timely basis could have a negative impact on our financial performance.

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.

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Failure to timely achieve regulatory approval for our products and introduce products to market could negatively affect our growth objectives and financial performance.

We face intense competition, and our failure to compete effectively could decrease our revenues and harm our profitability and results of operations.

The clinical diagnostics industry is highly competitive. Currently, the majority of diagnostic tests used by physicians and other health care providers are performed by large reference, public health and hospital laboratories. We expect that these laboratories will compete vigorously to maintain their dominance in the diagnostic testing market. In order to achieve market acceptance of our products, we will be required to demonstrate that our products provide accurate, cost-effective and time saving alternatives to tests performed by traditional laboratory procedures and products made by our competitors.

In the markets for clinical diagnostic products, a number of competitors, including F. Hoffman-La Roche Ltd. and its affiliate Roche Molecular Systems, Inc., which we refer to collectively as Roche, Abbott Laboratories, through its subsidiary Abbott Molecular Inc., which we refer to collectively as Abbott, BD, Siemens, QIAGEN N.V., bioMérieux, and Hologic, Inc., 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 affect 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 and received FDA approval of a multiplex real-time PCR assay to screen donated blood in December 2008. Our collaboration with Novartis also competes with blood banks and laboratories that have internally developed assays based on PCR technology, Ortho-Clinical Diagnostics, Inc., 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.

We believe the global blood screening market is maturing rapidly. We believe the competitive position of our blood screening collaboration with Novartis in the United States remains strong. However, outside of the United States, blood screening testing volume is generally more decentralized than in the United States, customer contracts typically turn over more rapidly and the number of new countries yet to adopt nucleic acid testing for blood screening is diminishing. As a result, we believe geographic expansion opportunities for our blood screening collaboration with Novartis may be narrowing and that we will face increasing price competition within the nucleic acid blood screening market.

Novartis also retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening using NAT. Prior to its merger with Novartis, Chiron Corporation, or Chiron, granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron also granted HIV and HCV licenses in

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the clinical diagnostics field to Bayer Healthcare LLC (now Siemens), together with the right to grant certain additional HIV and HCV sublicenses in the field to third parties. We believe Bayer s rights have now been assigned to Siemens as part of Bayer s December 2006 sale of its diagnostics business. Chiron also granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux) in the clinical diagnostics field. 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 and HIV assays and these licenses could affect the prices that can be charged for our products.

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 their quality 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. If we cannot obtain sufficient raw materials from our key suppliers, production of our own products may be delayed or disrupted. In addition, 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 supply interruption. We also have single source suppliers for proposed future products. Failure to maintain existing supply relationships or to obtain suppliers for our future products 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 oligonucleotides for HPV with Roche Molecular Systems. Each of these entities is an affiliate of Roche Diagnostics GmbH, one of our primary competitors.

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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, Inc., or KMC Systems, is the only manufacturer of our TIGRIS instrument. MGM Instruments, Inc., or MGM Instruments, is the only manufacturer of our LEADER series of luminometers. In addition, Stratec will be the only manufacturer of our development-stage PANTHER instrument system. 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 or MGM Instruments 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, Stratec or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its development or manufacturing operations or becomes insolvent or otherwise fails to supply us with products in sufficient quantities, 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 replace existing suppliers, increase our volumes or 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 and require regulatory approvals. 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 commercializing, or be unable to commercialize, our products 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 delay or preclude realization of product revenues from new products or result in substantial additional costs which could decrease our profitability.

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 European Union, or EU, foreign marketing authorizations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

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 March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. If we experience unexpected complications in conducting the trial, we may incur additional costs or experience delays or difficulties in receiving FDA approval. For example, we originally expected that enrollment and testing of approximately 7,000 women would be required to complete this trial. However, we actually enrolled approximately 13,000 women in the trial based on the actual prevalence of cervical disease observed. Although we completed baseline enrollment in the trial late in 2009, we cannot provide any assurances that the FDA

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will ultimately approve the use of our APTIMA HPV assay. Failure to obtain or delay in obtaining FDA approval of our APTIMA HPV assay could have a material adverse effect on our financial performance. In the third quarter of 2009, we began studies to validate our APTIMA Trichomonas vaginalis assay on the TIGRIS instrument system to permit registration and sale of the assay in the EU, as well as commenced a U.S. clinical trial for the Trichomonas assay on the TIGRIS instrument system. In June 2010, we received an EU CE mark for our APTIMA Trichomonas vaginalis assay on the TIGRIS instrument system. In the third quarter of 2010, we submitted a 510(k) application to the FDA for clearance of our Trichomonas assay. In the third quarter of 2009, we commenced a 500-patient U.S. clinical trial for our CE-marked PROGENSA PCA3 assay, which concluded enrollment in April 2010. In the third quarter of 2010, we submitted a premarket approval application to the FDA for our PROGENSA PCA3 assay. There can be no assurance that these assays will be approved for sale in the United States.

We are also 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.

Certain assay reagents may be sold in the United States as ASRs without 510(k) clearance or premarket approval from the FDA. However, the FDA restricts the sale of these ASR products to clinical laboratories certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments, or CLIA, and also restricts the types of products that can be sold as ASRs. In addition, each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory developed test. We currently offer several ASR products including 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 Incorporated. In September 2007, the FDA published guidance that defines 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 ASR products to the FDA for clearance or approval.

The use of our diagnostic products is also affected by CLIA and related federal and state regulations governing 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.

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. In December 2008, we recalled certain AccuProbe test kits after receiving a customer complaint indicating the customer

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had received a kit containing a probe reagent tube that appeared upon visual inspection to be empty. We confirmed that a manufacturing error had occurred, corrected the problem, recalled all potentially affected products, provided replacements and notified the FDA and other appropriate authorities.

Although none of our past product recalls had a material adverse effect on our business, our products may be subject to a future government-mandated recall or a voluntary recall, and any such recall 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 screening centers on a per donation basis, our profit margins are greater when a single test can be used to screen multiple donor samples.

We believe 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 amended and restated collaboration agreement with Novartis, we bear half of 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 our products are sold.

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 have 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. Total revenues from our blood screening collaboration with Novartis, which include product sales, collaborative research revenues and royalties, accounted for 41% of our revenues during the first nine months of 2010 and 42% of our total revenues for 2009. 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 do not receive any revenues directly from those entities. Novartis was our only customer that accounted for greater than 10% of total revenues during the first nine months of 2010. However, various state and city public health agencies accounted for an aggregate of 8% of our revenues during the first nine months of 2010 and 8% of our total revenues for 2009. Although state and city public health agencies are legally independent of each other, we believe they tend to act similarly with respect to their product purchasing decisions. We anticipate that our operating results will continue to depend to a significant extent upon revenues from a small number of customers. The loss of any of our key customers, or a significant reduction in sales volume or pricing to those customers, could significantly reduce our revenues.

Intellectual property rights on which we rely to protect the technologies underlying our products may be inadequate to prevent third parties from using our technologies or developing competing products.

Our success will depend in part on our ability to obtain patent protection for, or maintain the secrecy of, our proprietary products, processes and other technologies for the development of blood screening and clinical diagnostic products and instruments. Although we had more than 530 U.S. and foreign patents covering our products and technologies as of September 30, 2010, these patents, or any patents that we may own or license in the future, may not

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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 April 28, 2029 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 collaborators 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, adequate corrective remedies may not be 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 choose 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 such 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.

In October 2009, we filed a patent infringement action against BD in the U.S. District Court for the Southern District of California. The complaint alleges that BD s Viper XTR testing system infringes five of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint also

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alleges that BD s ProbeTec Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA assays used with the Viper XTR testing system infringe two of our U.S. patents covering penetrable caps for specimen collection tubes. Finally, the complaint alleges that BD has infringed our U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified; however, we have moved to dismiss this specific claim from the lawsuit, while maintaining all other claims. The complaint seeks monetary damages and injunctive relief. In March 2010, we filed a second complaint for patent infringement against BD in the U.S. District Court for the Southern District of California. The complaint alleges that BD s BD MAX System (formerly known as the HandyLab Jaguar system) infringes four of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint seeks monetary damages and injunctive relief. In June 2010, these two actions were consolidated into a single legal proceeding. There can be no assurances as to the final outcome of this litigation.

Pursuant to our 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 U.S. 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 September 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. In May 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. In September 2008, the parties to the pending litigation in the U.S. 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 we licensed from Institut Pasteur, or Novartis right to sell HIV blood screening tests.

The U.S. health care reform law could adversely affect our business, profitability and stock price.*

Comprehensive health care reform legislation has been signed into law in the United States. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of our assays and instruments. This tax is scheduled to take effect in 2013. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through spending cuts or other actions are unsuccessful, the increased tax burden would adversely affect our financial performance, which in turn could cause the price of our stock to decline.

Our indebtedness could adversely affect our financial health.

In February 2009, we entered into a credit agreement with Bank of America which provided for a one-year senior secured revolving credit facility in an amount of up to $180.0 million that is subject to a borrowing base formula. The revolving credit facility has a sub-limit for the issuance of letters of credit in a face amount of up to $10.0 million. In March 2009, we and Bank of America amended the credit facility to increase the amount which we may borrow from time to time under the credit agreement from $180.0 million to $250.0 million. In April 2009, we borrowed an additional $70.0 million under the revolving credit facility, bringing the total principal amount outstanding under the

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credit facility to $240.0 million as of September 30, 2010. In February 2010, our credit agreement with Bank of America was amended to extend the maturity date to February 2011.

Our indebtedness could have important consequences. For example, it could:

- increase our vulnerability to general adverse economic and industry conditions;
- have a material adverse effect on our business and financial condition if we are unable to service our indebtedness or refinance such indebtedness;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- place us at a disadvantage compared to our competitors that have less indebtedness; and
- expose us to higher interest expense in the event of increases in interest rates because indebtedness under our credit facility bears interest at a variable rate.

In addition, we must comply with certain affirmative and negative covenants under the credit agreement, including covenants that limit or restrict our ability to, among other things, merge or consolidate, change our business, and permit the borrowings to exceed a specified borrowing base, subject to certain exceptions as set forth in the credit agreement. If we default under the senior secured credit facility, because of a covenant breach or otherwise, the outstanding amounts thereunder could become immediately due and payable.

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, such defense may not be available for 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 an 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, or which our insurance policies do not cover, 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, 2010, we had approximately $506.8 million of long-lived assets, including $12.7 million of capitalized software, net of accumulated amortization, relating to our TIGRIS and PANTHER instruments, goodwill of $122.5 million, a $5.4 million investment in Qualigen, Inc., a $5.0 million investment in DiagnoCure, Inc., a $0.7 million investment in Roka Bioscience, Inc., a $50.0 million investment in Pacific Biosciences, and $152.9 million of capitalized licenses and manufacturing access fees, patents, acquired intangible assets and other long-term assets. Additionally, we had $70.4 million of land and buildings, $22.8 million of building improvements, $63.1 million of equipment and furniture and fixtures and $1.3 million in construction in progress. 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.

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

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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. In the past we have incurred, and in the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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

A change in accounting standards or practices, or a change in existing taxation rules or practices, can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, 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 reduce our profitability.

In recent years, we have incurred significant costs in connection with the development of blood screening and clinical diagnostic products, as well as our TIGRIS and PANTHER instrument systems. We expect our expense levels to remain high in connection with our research and development as we seek 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 current levels of profitability. Although we expect that our research and development expenses as a percentage of revenue will decrease in future periods, we may not be able to generate sufficient revenues to maintain current levels of profitability in the future. A potential reduction of profitability in the future could cause the market price of our common stock to decline.

Our marketable securities are subject to market and investment risks which may result in a loss of value.

We engage one or more third parties to manage some of our cash consistent with an investment policy that restricts investments to securities of high credit quality, with requirements placed on maturities and concentration by security type and issue. These investments are intended to preserve principal while providing liquidity adequate to meet our projected cash requirements. Risk of principal loss is intended to be minimized through diversified short and medium term investments of high quality, but these investments are not, in every case, guaranteed or fully insured. In light of recent changes in the credit market, some high quality short term investment securities, similar to the types of securities that we invest in, have suffered illiquidity, events of default or deterioration in credit quality. If our short term investment portfolio becomes affected by any of the foregoing or other adverse events, we may incur losses relating to these investments.

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 and capital expenditure and research and development requirements, we may in the future need to incur debt or issue equity in order to fund these requirements, as well as to make acquisitions and other investments. If we cannot obtain debt or equity financing on acceptable terms or are limited with respect to incurring debt or issuing equity, we may be unable to address gaps in our product offerings or improve our technology, particularly through acquisitions or investments.

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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, such financing 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.

Our products must be manufactured 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 in the future as we attempt to scale-up our manufacturing of a new product, and we may not achieve scale-up in a timely manner, 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 certain of 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 categories, 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 EU, 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 30% of our revenues during the first nine months of 2010 and 26% of our total revenues for 2009. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 57% of our international revenues during the first nine months of 2010 and 60% of our total international revenues for 2009.

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We encounter risks inherent in international operations. We expect a significant portion of our sales growth to come from expansion in international markets. If the value of the U.S. dollar increases relative to foreign currencies, our products could become less competitive in international markets. In addition, our international sales have increased as a result of our acquisition of Tepnel and other international expansion efforts. 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 we expect that it will continue to 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 may also 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 our customers 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.

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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 TMA technology is based on technology we have licensed from Stanford University. We enter into new licensing arrangements in the ordinary course of business to expand our product portfolio and access new technologies to enhance our products and develop new products. Many of these licenses provide us with exclusive rights to the subject technology or disease marker. If our license with respect to any of these technologies or markers is terminated for any reason, we may not be able to sell products that incorporate the technology. In addition, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license.

Our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Our ability to design products that target these diseases may depend on our ability to obtain the necessary rights from the third parties that make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT assays may be economically viable. If we are unable to access new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

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

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

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

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.

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 four manufacturing facilities, two of which are located in San Diego, California and the others are located in Stamford, Connecticut and Waukesha, Wisconsin. 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, tornadoes 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.

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In addition, we may also suffer disruptions in our ability to ship products to customers or otherwise operate our business as a result of other natural disasters, such as the recent eruption of the Icelandic volcano which necessitated the closing of a significant portion of the airspace over Europe for several days and caused the cancellation of thousands of airline flights during April 2010. Further eruptions by this Icelandic volcano or the occurrence of other natural disasters having a similar effect could harm our business and results of operations.

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 agents, 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 bylaws, 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.

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. In addition, we will have to maintain close coordination among our various departments and locations. If we fail to effectively manage our growth, it could adversely affect our ability to pursue business opportunities and expand our business.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have implemented an 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 or any unauthorized access to our information 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 in a secure environment, all of which could adversely affect our financial results, stock price and reputation.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, 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 continue to invest, in reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

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

The following table summarizes our common stock repurchase activity during the third quarter of 2010:

	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, 2010	205,383	$ 45.36	205,300	$ 38,389,058
August 1-31, 2010	371,554	46.12	346,300	22,458,377
September 1-30, 2010	224,700	46.90	224,700	11,920,573
Total [1] [2]	801,637		776,300	

[1] In February 2010, our Board of Directors authorized the repurchase of up

to $100.0 million of our common stock until December 31, 2010, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the three months ended September 30, 2010, we repurchased and retired approximately 776,300 shares under this program at an average price of $46.09 per share, or approximately $35.8 million in total. As of September 30, 2010, we have repurchased approximately 1,920,000 shares under this program since its inception at an average price of $45.87, or approximately $88.1 million in total.

(2) The difference between the total number of

shares purchased and the total number of shares purchased as part of publicly announced plans or programs is due to the shares of common stock withheld by us for the payment of taxes upon vesting of certain employees restricted stock. During the third quarter of 2010, we repurchased and retired 25,337 shares of our common stock, at an average price of $47.72, 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. As of September 30,

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2010, we had an aggregate of 162,193 shares of restricted stock and 60,000 shares of deferred issuance restricted stock awards outstanding.

Item 6. Exhibits

Exhibit Number	Description
2.1(1)	Agreement and Plan of Merger, dated as of October 6, 2009, by and among Gen-Probe Incorporated, Prodigy Acquisition Corp., Prodesse, Inc. and Thomas M. Shannon and R. Jeffrey Harris, as the Securityholders Representative Committee.*
3.1(2)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(3)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(4)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(5)	Certificate of Elimination of Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(2)	Specimen common stock certificate.
10.1	Second Amendment to Collaboration Agreement, dated June 11, 1998, by and between Siemens Healthcare Diagnostics Inc. and Gen-Probe Incorporated, effective as of July 1, 2009.**
10.2	Collaboration Agreement, dated as of June 15, 2010, by and between Gen-Probe Incorporated and Pacific Biosciences of California, Inc.**
31.1	Certification dated November 3, 2010, of Principal Executive Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification dated November 3, 2010, of Principal Financial Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification dated November 3, 2010, of Principal Executive Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification dated November 3, 2010, 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.
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

Filed herewith.

Furnished herewith.

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

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

(1) Incorporated by reference to Gen-Probe s Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on February 25, 2010.

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(2) Incorporated by reference to Gen-Probe s Amendment No. 2 to Registration Statement on Form 10 (File No. 000-49834) filed with the SEC on August 14, 2002.

(3) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q (File No. 001-31279) for the quarterly period ended June 30, 2004 filed with the SEC on August 9, 2004.

(4) Incorporated by reference to Gen-Probe s Current Report on Form 8-K filed with the SEC on February 18, 2009.

(5) 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 Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GEN-PROBE INCORPORATED

DATE: November 3, 2010

By: /s/ Carl W. Hull
Carl W. Hull
President, Chief Executive Officer and Director (Principal Executive Officer)

DATE: November 3, 2010

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