GEN PROBE INC
Form 10-Q
May 04, 2011

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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 March 31, 2011

OR

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

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 Office)	**92121-4362** (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 twelve 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 ninety 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 (Do not check if a smaller reporting company)	Smaller Reporting Company o

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

As of April 29, 2011, 47,941,970 shares of the registrant s common stock, $0.0001 par value per share, were outstanding.

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

	March 31, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 93,563	$ 59,690
Marketable securities	177,908	170,648
Trade accounts receivable, net of allowance for doubtful accounts of $405 and $355 at March 31, 2011 and December 31, 2010, respectively	59,633	54,739
Accounts receivable other	3,548	5,493
Inventories	65,180	66,416
Deferred income tax	13,774	13,634
Prepaid income tax	26	2,993
Prepaid expenses	13,837	11,672
Other current assets	5,698	5,148
Total current assets	433,167	390,433
Marketable securities, net of current portion	219,808	259,317
Property, plant and equipment, net	163,538	160,863
Capitalized software, net	14,014	13,981
Patents, net	12,327	12,450
Goodwill	150,639	150,308
Purchased intangibles, net	118,338	120,270
License, manufacturing access fees and other assets, net	62,427	60,175
Total assets	$ 1,174,258	$ 1,167,797
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 11,471	$ 14,614
Accrued salaries and employee benefits	19,066	26,825
Other accrued expenses	16,768	13,935
Income tax payable	7,649	634
Short-term borrowings	250,000	240,000
Deferred income tax	91	
Deferred revenue	1,460	1,166
Total current liabilities	306,505	297,174
Non-current income tax payable	8,864	8,315
Deferred income tax	27,308	29,775
Deferred revenue, net of current portion	2,318	2,500
Other long-term liabilities	7,149	6,654

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, 47,663,833 and 47,966,156 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	5	5
Additional paid-in capital	172,133	195,820
Accumulated other comprehensive (loss) income	(177)	678
Retained earnings	650,153	626,876
Total stockholders equity	822,114	823,379
Total liabilities and stockholders equity	$ 1,174,258	$ 1,167,797

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 March 31,	
	2011	**2010**
Revenues:		
Product sales	$ 138,112	$ 130,569
Collaborative research revenue	3,568	3,264
Royalty and license revenue	1,358	1,586
Total revenues	143,038	135,419
Operating expenses:		
Cost of product sales (excluding acquisition-related intangible amortization)	41,943	42,661
Acquisition-related intangible amortization	2,805	2,216
Research and development	28,963	29,681
Marketing and sales	16,522	14,781
General and administrative	18,153	14,679
Total operating expenses	108,386	104,018
Income from operations	34,652	31,401
Other income (expense):		
Investment and interest income	735	3,898
Interest expense	(503)	(546)
Gain on contingent consideration		1,745
Other income (expense), net	177	(159)
Total other income, net	409	4,938
Income before income tax	35,061	36,339
Income tax expense	11,784	12,146
Net income	$ 23,277	$ 24,193
Net income per share:		
Basic	$ 0.49	$ 0.49
Diluted	$ 0.48	$ 0.48
Weighted average shares outstanding:		
Basic	47,861	49,233
Diluted	49,004	49,739

See accompanying notes to consolidated financial statements

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

	Three Months Ended March 31,	
	2011	**2010**
Operating activities		
Net income	$ 23,277	$ 24,193
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	11,345	11,308
Amortization of premiums on investments, net of accretion of discounts	2,673	2,216
Stock-based compensation	6,036	5,902
Excess tax benefit from employee stock-based compensation	(1,425)	(1,596)
Deferred revenue	97	(833)
Deferred income tax	(615)	(1,360)
Gain on contingent consideration		(1,745)
Loss on disposal of property and equipment	24	47
Changes in assets and liabilities:		
Trade and other accounts receivable	(2,816)	7,696
Inventories	3,420	1,110
Prepaid expenses	(2,116)	(2,200)
Other current assets	(536)	(95)
Other long-term assets	(132)	(257)
Accounts payable	(3,196)	(8,065)
Accrued salaries and employee benefits	(7,847)	(5,256)
Other accrued expenses	(40)	(1,630)
Income tax payable	11,500	11,827
Other long-term liabilities	456	(575)
Net cash provided by operating activities	40,105	40,687
Investing activities		
Proceeds from sales and maturities of marketable securities	30,460	139,425
Purchases of marketable securities	(5,731)	(71,390)
Purchases of property, plant and equipment	(10,762)	(7,828)
Purchases of capitalized software	(780)	(1,089)
Purchases of intangible assets, including licenses and manufacturing access fees	(923)	(722)
Other	501	(310)
Net cash provided by investing activities	12,765	58,086
Financing activities		
Repurchase and retirement of common stock	(47,972)	(10,961)
Proceeds from issuance of common stock and employee stock purchase plan	17,390	16,912
Repurchase and retirement of restricted stock for payment of taxes	(358)	(39)
Excess tax benefit from employee stock-based compensation	1,425	1,596
Borrowings, net	10,000	

Net cash (used in) provided by financing activities	(19,515)	7,508
Effect of exchange rate changes on cash and cash equivalents	518	(1,620)
Net increase in cash and cash equivalents	33,873	104,661
Cash and cash equivalents at the beginning of period	59,690	82,616
Cash and cash equivalents at the end of period	$ 93,563	$ 187,277

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 March 31, 2011, and for the three month periods ended March 31, 2011 and 2010, 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, 2011.

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, 2010.

In accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 855, Subsequent Events, the Company evaluated subsequent events after the balance sheet date of March 31, 2011 and through the date and time its consolidated financial statements were issued on May 4, 2011.

Principles of Consolidation

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

In December 2010, the Company acquired Genetic Testing Institute, Inc. (GTI Diagnostics), a privately held Wisconsin corporation now known as Gen-Probe GTI Diagnostics, Inc. GTI Diagnostics has broadened and strengthened the Company s transplant diagnostics business, and has also provided the Company with access to new products in the specialty coagulation and transfusion-related blood bank markets. GTI Diagnostics results of operations have been included in the Company s consolidated financial statements beginning in December 2010.

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 consolidated financial statements beginning in October 2009.

In April 2009, the Company acquired 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 results of operations have been included in the Company s consolidated financial statements beginning in April 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 (loss) income. These adjustments will affect net income upon the sale or liquidation of the underlying investment.

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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; inventories; and goodwill and long-lived assets, including patent costs, capitalized software, purchased intangibles and licenses and manufacturing access fees. Actual results could differ from those estimates.

Segment Information

The Company currently operates in one business segment, the development, manufacturing, marketing, sales and support of molecular diagnostic products primarily to diagnose human diseases, screen donated human blood and ensure transplant compatibility. Although the Company s products comprise distinct product lines to serve different end markets within molecular diagnostics, the Company does not operate its business in operating segments. The Company is managed by a single functionally based management team that manages all aspects of the Company s business and reports directly to the Chief Executive Officer. For all periods presented, the Company operated in a single business segment. Revenue by product line is presented in Note 11.

Revenue Recognition

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

The Company manufactures blood screening products according to demand schedules provided by 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.

In most cases, 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 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. Installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation.

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

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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 evaluated for proper accounting treatment. In these arrangements, the Company records revenue as separate units of accounting if the delivered items have value to the customer on a stand-alone basis, and if the arrangement includes a general right of return relative to the delivered items, and delivery or performance of the undelivered items is considered probable and substantially within the Company s control. For transactions entered into prior to 2011, consideration was generally allocated to each unit of accounting based on its relative fair value when objective and reliable evidence of fair value existed for all units of accounting in an arrangement. The fair value of an item was generally the price charged for the product, if the item was sold on a stand-alone basis. When the Company was unable to establish fair value for delivered items or when fair value of undelivered items had not been established, revenue was deferred until all elements were delivered and services had been performed or until fair value could be objectively determined for any undelivered elements. Beginning in 2011, arrangement consideration is allocated at the inception of the arrangement to all deliverables using the relative selling price method that is based on a three-tier hierarchy. The relative selling price method requires that the estimated selling price for each deliverable be based on vendor-specific objective evidence (VSOE) of fair value, which represents the price charged for each deliverable when it is sold separately or for a deliverable not yet being sold separately, the price established by management having the relevant authority. When VSOE of fair value is not available, third-party evidence (TPE) of fair value is acceptable, or a best estimate of selling price if VSOE and TPE are not available. A best estimate of selling price should be consistent with the objective of determining the price at which the Company would transact if the deliverable were sold regularly on a stand-alone basis and should also take into account market conditions and company specific factors.

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 consideration that is contingent upon achievement of a milestone in its entirety is recorded as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. These criteria include (i) the consideration being earned should be commensurate with either the Company s performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company s performance to achieve the milestone, (ii) the consideration being earned should relate solely to past performance, (iii) the consideration being earned should be reasonable relative to all deliverables and payment terms in the arrangement, and (iv) the milestone should be considered in its entirety and cannot be bifurcated into substantive and non-substantive components. 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.

Stock-based Compensation

Stock-based compensation expense is recognized for restricted stock, deferred issuance restricted stock, performance stock awards, which include awards subject to performance conditions and/or market conditions, stock options, and shares purchasable under the Company s Employee Stock Purchase Plan (ESPP). Stock-based compensation expense for restricted stock, deferred issuance restricted stock, and performance condition stock awards is measured based on the closing fair market value of the Company s common stock on the date of grant. Stock-based compensation expense for market condition stock awards is measured based on the fair value of the award on the date of grant using a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple point variables

that determine the probability of satisfying the market condition stipulated in the grant and calculates the fair value of the award.

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The Company uses the Black-Scholes-Merton option pricing model to value stock options granted. The determination of the fair value of share-based payment awards on the date of grant using the Black-Scholes-Merton model is affected by the Company s stock price and the implied volatility on its traded options, as well as the input of other subjective assumptions. These assumptions include, but are not limited to, the expected term of stock options and the Company s expected stock price volatility over the term of the awards.

The Company used the following weighted average assumptions to estimate the fair value of stock options and performance stock awards granted under the Company s equity incentive plans and the shares purchasable under the Company s ESPP, as well as the resulting average fair values for the three month periods ended March 31, 2011 and 2010:

	Three Months Ended March 31,	
	2011	**2010**
Stock option plans		
Risk-free interest rate	1.7%	2.1%
Volatility	31%	32%
Dividend yield		
Expected term (years)	4.3	4.4
Resulting average fair value	$ 17.46	$ 12.71
Performance stock awards [(1)]		
Risk-free interest rate	1.3%	
Volatility	33%	
Dividend yield		
Expected term (years)	2.9	
Resulting average fair value	$ 82.58	$
ESPP		
Risk-free interest rate	0.2%	0.2%
Volatility	22%	26%
Dividend yield		
Expected term (years)	0.5	0.5
Resulting average fair value	$ 12.27	$ 9.65

(1) These assumptions apply to the Company s market condition stock awards granted in 2011. Performance condition stock awards granted in 2010 were valued at $42.66 based on the closing fair market value of the Company s common stock on the date of grant.

The Company s unrecognized stock-based compensation expense as of March 31, 2011, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards was approximately as follows (in thousands, except number of years):

Awards	**Weighted Average Remaining Expense Life (Years)**	**Unrecognized Expense as of March 31, 2011**
Options	2.9	$ 35,608
Employee stock purchase plan	0.2	80
Performance stock awards	2.8	7,694
Restricted stock	1.5	3,366

Deferred issuance restricted stock	1.7	993
Total	$	47,741

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The following table summarizes the stock-based compensation expense that the Company recorded in its consolidated statements of income for the three month periods ended March 31, 2011 and 2010 (in thousands):

	Three Months Ended March 31,	
	2011	2010
Cost of product sales	$ 788	$ 864
Research and development	1,792	1,679
Marketing and sales	612	802
General and administrative	2,844	2,557
Total	$ 6,036	$ 5,902

Net Income Per Share

Diluted net income per share is reported based on the more dilutive of the treasury stock or 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 under the two-class method 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 under the two-class method 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 688,000 and 4,179,000 for the three month periods ended March 31, 2011 and 2010, 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 month periods ended March 31, 2011 and 2010 (in thousands, except per share amounts):

	Three Months Ended March 31,					
	2011			2010		
	Income	Weighted Average Shares Outstanding	Per Share Amount	Income	Weighted Average Shares Outstanding	Per Share Amount
Net income	$ 23,277			$ 24,193		
Less: Earnings allocated to unvested stockholders	(35)			(101)		
Basic EPS						
Distributable income available to common stockholders	23,242	47,861	$ 0.49	24,092	49,233	$ 0.49
Effect of dilutive securities:						
Add back: Undistributed earnings allocated to unvested stockholders	35	89		101		

Dilutive stock options			1,054			506		
Less: Undistributed earnings reallocated to unvested stockholders					(100)			
Diluted EPS	**Common stock**	$ 23,277	49,004	$ 0.48	$ 24,093	49,739	$	0.48

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Adoption of Recent Accounting Pronouncements

Accounting Standards Update 2010-06

In January 2010, the FASB amended ASC Topic 820, Fair Value Measurements and Disclosures, to require reporting entities to make new disclosures about recurring and non-recurring 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 were effective for the Company as of January 1, 2011. Upon adoption, the guidance did not have a material impact on the Company s consolidated financial statements and is not expected to have a material impact on its future operating results.

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 Company elected to adopt this guidance prospectively, effective for the Company s fiscal year beginning January 1, 2011. Upon adoption, the guidance did not have a material impact on the Company s consolidated financial statements and is not expected to have a material impact on its future operating results.

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 may be applied retrospectively or prospectively for new or materially modified arrangements. The Company elected to adopt this guidance prospectively, effective for the Company s fiscal year beginning January 1, 2011. Upon adoption, the guidance did not have a material impact on the Company s consolidated financial statements and is not expected to have a material impact on its future operating results.

Note 2 Business Combination

The acquisition below was accounted for as a business combination and, accordingly, the Company has included the results of operations of the acquired entity 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 acquisition does not meet the quantitative materiality tests under Regulation S-X.

Acquisition of GTI Diagnostics

In December 2010, the Company acquired GTI Diagnostics, a privately held specialty diagnostics company focused on the transplantation, specialty coagulation and transfusion-related blood bank markets, for $53.0 million on a net-cash basis. As a result of the acquisition, GTI Diagnostics became a wholly owned subsidiary of the Company. The Company financed the acquisition with cash on hand.

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The purchase price allocation for the acquisition of GTI Diagnostics 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 during the remainder of 2011. The preliminary allocation of the purchase price for the Company s acquisition of GTI Diagnostics is as follows (in thousands):

Total purchase price	$ 53,000
Net working capital	$ 7,881
Fixed assets	1,001
Goodwill	28,005
Deferred tax liabilities	(11,137)
Other intangible assets	32,100
Liabilities assumed	(4,850)
Allocated purchase price	$ 53,000

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

Patents	$ 10,600
In-process research and development	11,900
Customer relationships	3,500
Trade secrets	6,100
Total	$ 32,100

The amortization periods for the acquired identifiable intangible assets with definite lives are as follows: six to nine years for patents, ten years for customer relationships, 20 years for trade secrets, and an estimated life to be determined for each in-process research and development project (to commence upon commercialization of the associated product). The Company is amortizing 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 business and the historical and projected growth of revenues and related cash flows. 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 trade secrets 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 licensor of the asset 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 asset in its current use and is based on savings from owning the asset, or relief from royalties that would be paid to the asset owner. The fair value assigned to patents, 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 ranged from 13 to 16 percent.

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The estimated amortization expense for the acquired identifiable intangible assets over future periods, excluding the in-process research and development assets due to uncertainty with respect to the commercialization of such assets, is as follows (in thousands):

Years Ending December 31,	
Remainder of 2011	$ 1,490
2012	1,987
2013	1,987
2014	1,987
2015	1,987
Thereafter	10,303
Total	$ 19,741

Changes in Goodwill Resulting From Acquisitions

The $53.0 million purchase price for GTI Diagnostics exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company allocated $28.0 million to goodwill. Included in this initial goodwill amount was $11.1 million primarily related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired identifiable intangible assets.

Changes in goodwill for the three months ended March 31, 2011 were as follows (in thousands):

Goodwill balance as of December 31, 2010	$ 150,308
Changes due to foreign currency translation	331
Goodwill balance as of March 31, 2011	$ 150,639

Note 3 Consolidation of UK Operations

Following its acquisition of Tepnel in April 2009, the Company had 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 $4.2 million and be incurred over a two-year period, as the consolidation will occur in phases. These expenses will include termination costs, including severance costs related to the elimination of certain redundant positions and relocation costs for certain key employees, and site closure costs.

During the three months ended March 31, 2011, the Company recorded approximately $0.4 million and $0.7 million of termination costs and site closure costs, respectively. These amounts are included in general and administrative expenses in the Company s consolidated statements of income. As of March 31, 2011, the Company has recorded approximately $0.9 million and $1.3 million of cumulative termination costs and site closure costs, respectively, related to its UK consolidation activities.

The following table summarizes the restructuring activities accounted for under ASC 420 for the three months ended March 31, 2011, as well as the remaining restructuring accrual recorded on the Company s consolidated balance sheets at March 31, 2011 (in thousands):

	Termination Costs	**Site Closure Costs**	**Total**
Restructuring reserves at December 31, 2010	$ 298	$ 79	$ 377
Charged to expenses	371	711	1,082

Amounts paid	(518)	(380)	(898)
Foreign currency translation	1		1
Restructuring reserves at March 31, 2011	$ 152	$ 410	$ 562

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Note 4 Balance Sheet Information

The following tables provide details of selected balance sheet items as of March 31, 2011 and December 31, 2010 (in thousands):

Inventories

	March 31, 2011	December 31, 2010
Raw materials and supplies	$ 18,238	$ 16,915
Work in process	24,642	21,446
Finished goods	22,300	28,055
Inventories	$ 65,180	$ 66,416

Property, Plant and Equipment, Net

	March 31, 2011	December 31, 2010
Land	$ 19,287	$ 19,287
Building	80,010	80,010
Machinery and equipment	199,650	195,927
Building improvements	48,671	48,217
Furniture and fixtures	22,451	21,999
Construction in-progress	3,863	1,855
Property, plant and equipment, at cost	373,932	367,295
Less: accumulated depreciation and amortization	(210,394)	(206,432)
Property, plant and equipment, net	$ 163,538	$ 160,863

Purchased Intangibles, Net

	March 31, 2011	December 31, 2010
Purchased intangibles, at cost	$ 167,110	$ 166,541
Less: accumulated amortization	(48,772)	(46,271)
Purchased intangibles, net	$ 118,338	$ 120,270

License, Manufacturing Access Fees and Other Assets, Net

	March 31, 2011	December 31, 2010
License and manufacturing access fees	$ 67,806	$ 64,259
Investment in Qualigen	5,404	5,404
Investment in DiagnoCure	5,000	5,000

Investment in Roka	725	725
Other assets	10,763	8,782
License, manufacturing access fees and other assets, at cost	89,698	84,170
Less: accumulated amortization	(27,271)	(23,995)
License, manufacturing access fees and other assets, net	$ 62,427	$ 60,175

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Other Accrued Expenses

	March 31, 2011	December 31, 2010
Royalties	$ 3,422	$ 3,315
Capitalized license fees	3,000	
Research and development	3,452	3,385
Professional fees	1,474	1,182
Marketing	855	1,177
Interest	991	896
Warranty	295	373
Other	3,279	3,607
Other accrued expenses	$ 16,768	$ 13,935

Note 5 Marketable Securities

The Company s marketable securities include equity securities, treasury securities, tax advantaged municipal securities and Federal Deposit Insurance Corporation (FDIC) insured corporate bonds with a minimum Moody s credit rating of A3 or a Standard & Poor s credit rating of A-. 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 March 31, 2011, the Company s portfolio 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 marketable securities as of March 31, 2011 and December 31, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
March 31, 2011				
Debt securities	$ 353,048	$ 643	$ (2,010)	$ 351,681
Equity securities	50,000		(3,965)	46,035
	$ 403,048	$ 643	$ (5,975)	$ 397,716

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2010				
Debt securities	$ 380,242	$ 561	$ (2,968)	$ 377,835
Equity securities	50,000	2,130		52,130
	$ 430,242	$ 2,691	$ (2,968)	$ 429,965

The following table shows the estimated fair values and gross unrealized losses as of March 31, 2011 for the Company s investments in individual debt 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 (in thousands):

Less than 12 Months		More than 12 Months	
Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
$ 196,344	$ (2,009)	$ 2,350	$ (1)

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At March 31, 2011 and December 31, 2010, the Company had 83 and 110 marketable debt securities, respectively, in an unrealized loss position. Of the 83 securities in an unrealized loss position at March 31, 2011, the average estimated fair value and average unrealized loss was $2.4 million and $24,000, respectively. Of the 110 securities in an unrealized loss position at December 31, 2010, the average estimated fair value and average unrealized loss was $2.1 million and $27,000, respectively. The decrease in the number of debt securities held in an unrealized loss position from 2010 to 2011 is due to the timing of purchases and sales of the Company s debt securities in 2011, along with increases in market interest rates.

The contractual terms of the debt securities held by the Company 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 debt securities with a current unrealized loss position to be other-than-temporarily impaired at March 31, 2011 because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost.

The following table shows the current and non-current classification of the Company s marketable securities as of March 31, 2011 and December 31, 2010 (in thousands):

	March 31, 2011	December 31, 2010
Current	$ 177,908	$ 170,648
Non-current	219,808	259,317
Total marketable securities	$ 397,716	$ 429,965

As of March 31, 2011, the Company held non-current marketable debt securities and marketable equity securities of $173.8 million and $46.0 million, respectively. As of December 31, 2010, the Company held non-current marketable debt securities and marketable equity securities of $207.2 million and $52.1 million, respectively. Investments in an unrealized loss position deemed to be temporary at March 31, 2011 and December 31, 2010 that have a contractual maturity of greater than 12 months have been classified on the Company s consolidated balance sheets 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 marketable debt securities and marketable equity securities are classified as available-for-sale.

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 month periods ended March 31, 2011 and 2010 (in thousands):

	Three Months Ended March 31,	
	2011	2010
Proceeds from sale of marketable securities	$ 30,153	$ 140,581
Gross realized gains	$ 2	$ 2,227
Gross realized losses	(356)	
Net realized (loss) gain	$ (354)	$ 2,227

Note 6 Fair Value Measurements

The Company determines the fair value of its assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (exit price) in the principal or most advantageous market for the asset or 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 carrying amounts of financial instruments such as cash equivalents, accounts receivable, prepaid and other current assets, accounts payable and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. 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 equity securities, treasury securities, tax advantaged municipal securities, FDIC insured corporate bonds and money market funds. When available, the Company 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.

In connection with a collaboration agreement the Company entered into with Pacific Biosciences of California, Inc. (Pacific Biosciences) in June 2010, the Company 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, which now trades on the NASDAQ Global Select Market under the symbol PACB . As a result of the initial public offering, the preferred stock held by the Company was converted into common stock. During the quarter ended December 31, 2010, the Company reclassified its investment in Pacific Biosciences from a Level 3 investment to a Level 1 investment. The Company s investment in Pacific Biosciences, which totaled $46.0 million as of March 31, 2011, is included in Marketable securities, net of current portion, on the Company s consolidated balance sheets. The Company s investment in Pacific Biosciences common stock was subject to a customary lock-up period, which generally prohibited the Company from selling or otherwise transferring such securities for a 180 day period after the date of the final prospectus relating to Pacific Biosciences initial public offering. This lock-up period expired in April 2011. As of May 4, 2011, the Company continues to hold this investment.

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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 March 31, 2011 and December 31, 2010 (in thousands):

	Fair Value Measurements at March 31, 2011			
	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	$	$ 26,785	$	$ 26,785
Marketable securities				
Equity securities	46,035			46,035
Municipal securities		351,681		351,681
Total marketable securities	46,035	351,681		397,716
Deferred compensation plan assets		6,587		6,587
Total assets at fair value	$ 46,035	$ 385,053	$	$ 431,088
Liabilities:				
Deferred compensation plan liabilities	$	$ 6,044	$	$ 6,044
Total liabilities at fair value	$	$ 6,044	$	$ 6,044

	Fair Value Measurements at December 31, 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	$	$ 1,211	$	$ 1,211
Marketable securities				
Equity securities	52,130			52,130
Treasury securities		7,891		7,891
Municipal securities		366,300		366,300

Corporate obligations		3,644		3,644
Total marketable securities	52,130	377,835		429,965
Deferred compensation plan assets		6,298		6,298
Total assets at fair value	$ 52,130	$ 385,344	$	$ 437,474
Liabilities:				
Deferred compensation plan liabilities	$	$ 6,246	$	$ 6,246
Total liabilities at fair value	$	$ 6,246	$	$ 6,246

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 a non-recurring basis and therefore are not included in the table above. Such instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (for example, when there is evidence of impairment).

Equity Investment in 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

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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 DiagnoCure s 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 March 31, 2011, 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.

Roka Bioscience, Inc.

In September 2009, the Company spun-off its industrial testing assets to Roka Bioscience, Inc. (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 considers Roka to be a variable interest entity in accordance with ASC Topic 810, Consolidation. The Company is not the primary beneficiary of Roka and therefore has not consolidated Roka s financial position or results of operations in the Company s consolidated financial statements. The Company s investment in Roka totaled approximately $0.7 million as of March 31, 2011, and is included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

In April 2011, the Company purchased approximately $4.0 million of Roka s Series C preferred stock as a participant in Roka s Series C preferred stock round of financing that raised a total of approximately $20.0 million. Following this Series C investment, the Company owns shares of preferred stock representing approximately 19% of Roka s capital stock on a fully diluted basis and its investment in Roka totaled approximately $4.7 million.

Qualigen, Inc.

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 March 31, 2011, 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.

Note 7 Borrowings

In February 2009, the Company entered into a credit agreement with Bank of America, N.A. (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. Subject to the terms of the credit agreement, including the amount of funds that the Company is

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permitted to borrow from time to time under the credit agreement, 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 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. The term of the credit facility with Bank of America has been extended twice and currently expires in February 2012. As of December 31, 2010, the total principal amount outstanding under the revolving credit facility was $240.0 million. The Company borrowed the remaining $10.0 million under the revolving credit facility during the first quarter of 2011. As a result, the total principal amount outstanding under the revolving credit facility was $250.0 million as of March 31, 2011 and the interest rate payable on such outstanding amount was approximately 0.86%.

Note 8 Income Tax

As of March 31, 2011, the Company had total gross unrecognized tax benefits of $11.2 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 $8.7 million. The Company s federal tax returns for the 2007 through 2009 tax years, California tax returns for the 2005 through 2009 tax years, and UK tax returns for the 2006 through 2009 tax years are subject to future examination.

Note 9 Contingencies

Contingent Consideration

In connection with the acquisition of Prodesse, the Company was originally obligated to make certain contingent payments to Prodesse securityholders of up to $25.0 million based on multiple performance measures, including commercial and regulatory milestones. As a result of the failure to achieve a specified milestone, the maximum amount of contingent consideration the Company may be required to pay for its acquisition of Prodesse has been reduced to $15.0 million.

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 is $0 at March 31, 2011 because the Company does not currently expect to make any further milestone payments related to its acquisition of Prodesse. Future milestone payments, if any, will occur by the second quarter of 2012.

Litigation

The Company is a party to the following litigation and may also be involved in other litigation arising in the ordinary course of business from time to time. 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.

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Becton, Dickinson and Company

In October 2009, the Company filed a patent infringement action 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) 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. 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 alleging that BD s BD MAX System™ (formerly known as the HandyLab Jaguar system) infringes four of its U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The second complaint also 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.

Note 10 Stockholders Equity

Changes in stockholders equity for the three months ended March 31, 2011 were as follows (in thousands):

Balance at December 31, 2010	$ 823,379
Net income	23,277
Other comprehensive income (loss), net	(855)
Proceeds from the issuance of common stock and ESPP	17,390
Issuance of common stock to board members	87
Repurchase and retirement of common stock	(47,972)
Repurchase and retirement of restricted stock for payment of taxes	(358)
Stock-based compensation	5,910
Stock-based compensation income tax benefits	1,256
Balance at March 31, 2011	$ 822,114

Comprehensive Income

All components of comprehensive income, including net income, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income (loss), which includes certain changes in stockholders equity, such as foreign currency translation of the Company s wholly owned subsidiaries financial statements and unrealized gains and losses on 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 month periods ended March 31, 2011 and 2010 were as follows (in thousands):

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	Three Months Ended March 31,	
	2011	2010
Net income, as reported	$ 23,277	$ 24,193
Other comprehensive loss:		
Foreign currency translation adjustment	2,328	(2,854)
Change in net unrealized gain on available-for-sale securities during the period	(3,413)	(2,649)
Reclassification adjustments:		
Realized gain on available-for-sale securities, net of tax	230	1,448
Total other comprehensive loss, net	(855)	(4,055)
Comprehensive income	$ 22,422	$ 20,138

Stock Options

A summary of the Company s stock option activity for all option plans for the three months ended March 31, 2011 is as follows (in thousands, except per share data and number of years):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010	5,700	$ 46.56		
Granted	882	63.26		
Exercised	(420)	41.38		
Cancelled	(21)	46.02		
Outstanding at March 31, 2011	6,141	$ 49.31	4.5	$ 104,737
Exercisable at March 31, 2011	3,782	$ 47.28	3.6	$ 72,209

Restricted Stock and Deferred Issuance Restricted Stock

A summary of the Company s restricted stock and deferred issuance restricted stock award activity for the three months ended March 31, 2011 is as follows (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2010	121	$ 54.41
Granted	1	59.40
Vested and exercised	(8)	53.32
Cancelled		

Unvested at March 31, 2011	114	$	54.55

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Performance Stock Awards

A summary of the Company s performance stock award activity for the three months ended March 31, 2011 is as follows (in thousands, except per share data):

	Number of Shares	Maximum Shares Eligible to Receive	Weighted Average Grant Date Fair Value
Unvested at December 31, 2010	65	97	$ 42.66
Awarded	91	182	82.58
Issued	(12)	(12)	42.66
Cancelled	(28)	(60)	42.66
Unvested at March 31, 2011	116	207	$ 74.04

Beginning in 2010, the Company transitioned from its historical practice of granting certain senior Company employees annual restricted stock awards with time-based vesting provisions only, to granting these employees the right to receive a designated number of shares of Company common stock based on the achievement of specific performance criteria over a defined performance period (the Performance Stock Awards). All Performance Stock Awards have been 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 of 1986, as amended.

In February 2010, the Compensation Committee of the Board of Directors of the Company granted certain senior Company employees Performance Stock Awards based on the Company s 2010 revenues, earnings per share and return on invested capital (collectively, the 2010 Performance Stock Criteria). Each recipient was eligible to receive between zero and 150% of the target number of shares of Company common stock subject to the applicable award based on actual performance as measured against the 2010 Performance Stock Criteria. In February 2011, the Company issued an aggregate of approximately 37,500 shares of Company common stock to award recipients based on actual performance. One-third of the issued shares vested on the date of issuance, one-third of the shares will vest on the first anniversary of the date of issuance and one-third of the shares will vest on the second anniversary of the date of issuance, as long as the award recipient is employed by the Company on each such vesting date.

In February 2011, the Compensation Committee granted certain senior Company employees Performance Stock Awards based on the Company s adjusted relative stockholder return in comparison to a defined market index over a three-year performance period (the 2011 Performance Stock Criteria). Each recipient is eligible to receive between zero and 200% of the target number of shares of Company common stock subject to the applicable award based on actual performance as measured against the 2011 Performance Stock Criteria. Performance under the awards will be measured annually from January 1, 2011 for performance intervals of one, two and three years, with each performance interval representing one-third of the total potential award. Shares issued following each annual performance measurement will be immediately vested upon issuance. Award recipients will be eligible to receive shares issued pursuant to such awards, as long as the award recipient is employed by the Company on each such issuance date.

Stock Repurchase Programs

In February 2011, the Company s Board of Directors authorized the repurchase of up to $150.0 million of the Company s common stock until December 31, 2011, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. As of March 31, 2011, approximately 756,000 shares have been repurchased under this program at an average price of $63.49 per share, or approximately $48.0 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 was no minimum or maximum number of shares to be repurchased under the program. The Company completed the program

in December 2010, repurchasing and retiring approximately 2,165,000 shares since the program s inception at an average price of $46.16 per share, or approximately $99.9 million in total.

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Note 11 Product Line and Significant Customer Information

The Company currently operates in one business segment, the development, manufacturing, marketing, sales and support of molecular diagnostic products primarily to diagnose human diseases, screen donated human blood and ensure transplant compatibility.

Product sales by product line for the three month periods ended March 31, 2011 and 2010 were as follows (in thousands):

	Three Months Ended March 31,			
	2011		2010	
	$	%	$	%
Clinical diagnostics	88,290	64%	76,893	59%
Blood screening	46,705	34%	49,568	38%
Research products and services	3,117	2%	4,108	3%
Total product sales	138,112	100%	130,569	100%

During the three month periods ended March 31, 2011 and 2010, 35% and 39%, respectively, of total revenues were from Novartis. No other customer accounted for more than 10% of the Company s revenues during the three month periods ended March 31, 2011 and 2010.

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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. Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plans, intends, estimates, would, continue, seeks or anticipates, or other similar words (including their use in the negative), or by discussions future matters, such as the development and commercialization of new products, technology enhancements, regulatory approvals or clearance, possible changes in legislation, expectations for future growth, estimates of future revenues, expenses, profits, cash flows or balance sheet items, or other financial guidance and other statements that are not historical. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. We assume no obligation to update any forward-looking statements.

The following information should be read in conjunction with our March 31, 2011 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, 2010 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, 2010. 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, 2010. 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 molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility. Our molecular diagnostic products 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 nucleic acid tests, or NATs, 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 and 2010, 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 in April 2009, offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse added a portfolio of real-time polymerase chain reaction, or real-time PCR, products for detecting influenza and other infectious organisms. In addition, in December 2010, we acquired GTI Diagnostics, a manufacturer of certain of our transplant diagnostic products, in addition to specialty coagulation and transfusion-related blood bank products.

In blood screening, we develop and manufacture the PROCLEIX assays, which are used to detect human immunodeficiency virus (type 1), or HIV-1, the hepatitis C virus, or HCV, the hepatitis B virus, or HBV, and the West Nile virus, or WNV, in donated human blood. Our blood screening products are marketed worldwide by Novartis under Novartis trademarks. 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 NAT testing systems 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 and commercializing our next-generation PANTHER instrument, which is

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designed to be a versatile, fully automated NAT system for low- to mid-volume laboratories. The PANTHER instrument was CE-marked and launched in Europe in the fourth quarter of 2010.

Our development pipeline includes products to detect:

human papillomavirus, or HPV, which can cause cervical cancer;

gene-based markers for prostate cancer;

certain respiratory infections;

antigens and antibodies that are used to determine transplant and transfusion compatibility; and

coagulation disorders.

Recent Events

Financial Results

Product sales for the first quarter of 2011 were $138.1 million, compared to $130.6 million in the same period of the prior year, an increase of 6%. Total revenues for the first quarter of 2011 were $143.0 million, compared to $135.4 million in the same period of the prior year, an increase of 6%. Net income for the first quarter of 2011 was $23.3 million ($0.48 per diluted share), compared to $24.2 million ($0.48 per diluted share) in the same period of the prior year, a decrease of 4%.

Our total revenues, net income and fully diluted earnings per share during the first quarter of 2011 included the results of operations of GTI Diagnostics, which were not included in our results of operations for the comparable period of the prior year.

Acquisition of GTI Diagnostics

In December 2010, we acquired Genetic Testing Institute, Inc., a privately held Wisconsin corporation which we refer to herein as GTI Diagnostics, for approximately $53.0 million on a net-cash basis. Our acquisition of GTI Diagnostics has broadened and strengthened our transplant diagnostics business, and has also provided us access to new products in the specialty coagulation and transfusion-related blood bank markets.

Stock Repurchase Program

In February 2011, our Board of Directors authorized the repurchase of up to $150.0 million of our common stock until December 31, 2011, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the first quarter of 2011, we repurchased and retired approximately 756,000 shares under this program at an average price of $63.49 per share, or approximately $48.0 million in total.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and 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, valuation of inventories and long-lived assets, including license and manufacturing access fees, patent costs and capitalized software, equity investments in publicly and privately held companies, accrued liabilities, income tax and the valuation of stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

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We believe there have been no significant changes during the first quarter of 2011 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, 2010.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements impacting our business, see Note 1 of the Notes to Consolidated Financial Statements included elsewhere in this report.

Results of Operations

Product Sales

(Dollars in millions)	**Three Months Ended March 31,**			
	2011	**2010**	**$ Change**	**% Change**
Clinical diagnostics	$ 88.3	$ 76.9	$ 11.4	15%
Blood screening	46.7	49.6	(2.9)	-6%
Research products and services	3.1	4.1	(1.0)	-24%
Total product sales	$ 138.1	$ 130.6	$ 7.5	6%
As a percent of total revenues	97%	96%		

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, other infectious disease, transplant diagnostics, and genetic testing 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 by 6% during the first quarter of 2011 compared to the same period of the prior year. The increase was primarily attributed to higher contributions from product lines of our acquired companies and APTIMA assay sales, offset by lower blood screening and research products and services revenues.

Clinical Diagnostic Product Sales

Clinical diagnostic product sales, including assay, instrument, and ancillary sales, represented $88.3 million, or 64% of product sales during the first quarter of 2011, compared to $76.9 million, or 59% of product sales during the same period of the prior year. The $11.4 million increase is primarily attributed to the addition of product sales from our acquired company, GTI Diagnostics, an increase in product sales from infectious disease products, and increased APTIMA sales.

Clinical diagnostic product sales were not materially affected by exchange rate impacts during the first quarter of 2011 as compared to the same period in the prior year.

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Blood Screening Product Sales

Blood screening product sales, including assay, instrument, and ancillary sales, represented $46.7 million, or 34% of product sales during the first quarter of 2011, compared to $49.6 million, or 38% of product sales during the same period of the prior year. The $2.9 million decrease is primarily attributed to a decrease in the sale of blood screening-related instrumentation in the current period.

Blood screening product sales were negatively affected by unfavorable estimated exchange rate impacts of $0.3 million during the first quarter of 2011 as compared to the same period in the prior year, primarily due to a stronger U.S. dollar versus the Euro.

Research Products and Services

We established an additional category of product sales as a result of our acquisition of Tepnel in 2009, 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 during the first quarter of 2011, compared to $4.1 million during the same period of the prior year. The $1.0 million decrease is primarily due to lower levels of pharmaceutical service work performed in the current period.

Collaborative Research Revenue

(Dollars in millions)	**Three Months Ended March 31,**			
	2011	**2010**	**$ Change**	**% Change**
Collaborative research revenue	$ 3.6	$ 3.3	$ 0.3	9%
As a percent of total revenues	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.

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 costs associated with collaborative research revenue.

Collaborative research revenue increased 9% during the first quarter of 2011 compared to the same period of the prior year. The $0.3 million increase was primarily due to increased reimbursements from Novartis for shared development expenses 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.

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Royalty and License Revenue

(Dollars in millions)	Three Months Ended March 31,			
	2011	2010	$ Change	% Change
Royalty and license revenue	$ 1.4	$ 1.6	$ (0.2)	-13%
As a percent of total revenues	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. 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 by 13% during the first quarter of 2011 compared to the same period of the prior year. The $0.2 million decrease was primarily a result of lower collaboration royalties received from Novartis related to 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 March 31,			
	2011	2010	$ Change	% Change
Cost of product sales	$ 41.9	$ 42.7	$ (0.8)	-2%
Gross profit margin as a percent of product sales	70%	67%		

Cost of product sales includes direct material, direct labor and manufacturing overhead associated with the production of inventories. Cost of product sales may fluctuate significantly in different 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 material, additional costs related to initial production quantities of new products after achieving FDA approval, instrument and software amortization, and contractual adjustments, such as instrumentation costs, instrument service costs, warranty costs and royalties. 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.

Cost of product sales decreased 2% during the first quarter of 2011 compared to the same period in the prior year. The $0.8 million decrease was primarily due to lower instrumentation sales and lower research products and services revenue. These lower costs were partially offset by additional cost of product sales related to our acquired GTI Diagnostics business.

Our gross profit margin as a percentage of product sales increased to 70% during the first quarter of 2011 from 67% during the same period in the prior year. The increase in gross profit margin as a percentage of product sales was principally attributed to higher sales from our infectious disease products and lower sales of lower margin instrumentation. The positive impact of these factors was partially offset by an increase in test shipments as a proportion of our overall share of blood screening revenues.

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A portion of our blood screening revenues is attributable to sales of TIGRIS instruments to Novartis, which totaled $2.0 million and $4.1 million during the first quarter of 2011 and 2010, respectively. Under our collaboration agreement with Novartis, we sell TIGRIS instruments to them 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 in the periods when 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 March 31,			
			$	%
	2011	2010	Change	Change
Acquisition-related intangible amortization	$ 2.8	$ 2.2	$ 0.6	27%
As a percent of total revenues	2%	2%		

Amortization expense related to our acquired intangible assets increased 27% during the first quarter of 2011 as compared to the same period in the prior year. The $0.6 million increase was attributable to an additional three months of amortization expense resulting from our acquisition of GTI Diagnostics in December 2010. Our acquired intangible assets are amortized using the straight-line method over their estimated useful lives, which range from 5 to 20 years.

Research and Development

(Dollars in millions)	Three Months Ended March 31,			
			$	%
	2011	2010	Change	Change
Research and development	$ 29.0	$ 29.7	$ (0.7)	-2%
As a percent of total revenues	20%	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.

R&D expenses decreased 2% during the first quarter of 2011 compared to the same period in the prior year. The $0.7 million decrease was primarily related to a decline in development expenses due to the wind-down of clinical trials for our HPV, PCA3, and Trichomonas assays during 2010, partially offset by additional R&D expenses related to our acquired GTI Diagnostics business.

Marketing and Sales

(Dollars in millions)	Three Months Ended March 31,			
			$	%
	2011	2010	Change	Change
Marketing and sales	$ 16.5	$ 14.8	$ 1.7	11%
As a percent of total revenues	12%	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 11% during the first quarter of 2011 compared to the same period in the prior year. The $1.7 million increase is primarily attributed to an increase in salaries, personnel-related expenses, and marketing activities due to our acquired GTI Diagnostics business and continued investment in international expansion, primarily in Western Europe.

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General and Administrative

(Dollars in millions)	Three Months Ended March 31,			
	2011	2010	$ Change	% Change
General and administrative	$ 18.2	$ 14.7	$ 3.5	24%
As a percent of total revenues	13%	11%		

Our general and administrative, or G&A, expenses include expenses for finance, legal, strategic planning and business development, public relations and human resources.

G&A expenses increased 24% during the first quarter of 2011 compared to the same period in the prior year. The $3.5 million increase is primarily attributable to higher G&A costs associated with the consolidation of our United Kingdom operations, our acquired GTI Diagnostics business, and costs relating to litigation and patent prosecution.

Total Other Income, Net

(Dollars in millions)	Three Months Ended March 31,			
	2011	2010	$ Change	% Change
Investment and interest income	$ 0.7	$ 3.9	$ (3.2)	-82%
Interest expense	(0.5)	(0.5)		0%
Gain on contingent consideration		1.7	(1.7)	-100%
Other income (expense), net	0.2	(0.2)	0.4	-200%
Total other income, net	$ 0.4	$ 4.9	$ (4.5)	-92%

Total other income, net, decreased 92% during the first quarter of 2011 compared to the same period in the prior year. The $3.2 million decrease in investment and interest income is primarily attributed to lower net realized gains on sales of marketable securities, decreased interest income due to lower investment balances in 2011 as a result of the sale of investments to fund our recent acquisitions, cash used for our stock repurchase program, and higher purchase premium amortizations arising from increased market demand for tax-advantaged municipal bonds.

We recorded a non-cash gain of $1.7 million during the first quarter of 2010 as a result of a reduction in the fair value of the contingent consideration liability related to our acquisition of Prodesse. The fair value of the contingent consideration liability is $0 as of March 31, 2011 because we do not currently expect to make any further milestone payments related to our acquisition of Prodesse. Future milestone payments, if any, will occur by the second quarter of 2012.

Income Tax Expense

(Dollars in millions)	Three Months Ended March 31,			
	2011	2010	$ Change	% Change
Income tax expense	$ 11.8	$ 12.1	$ (0.3)	-2%
As a percent of income before tax	34%	33%		

Our effective tax rate during the first quarter of 2011 increased as compared to the same period in the prior year primarily due to contingent consideration adjustments in 2010 that are generally not taxable.

Liquidity and Capital Resources

	March 31, 2011	December 31, 2010
	(In millions)	

Cash, cash equivalents and current marketable securities	$ 271.5	$ 230.3
Working capital	126.7	93.3
Current ratio	1.4:1	1.3:1

Our working capital at March 31, 2011 increased $33.4 million from December 31, 2010. This increase in working capital can be attributed primarily to an increase in cash and cash equivalents during the quarter. During the

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first quarter of 2011, we generated $40.1 million and $12.8 million of cash from operating and investing activities, respectively. These increases were offset by $19.5 million of cash used in financing activities.

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 equity securities, 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-. Our investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At March 31, 2011, our portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody s.

	Three Months Ended March 31,		
	2011	2010	$ Change
	(In millions)		
Cash provided by (used in):			
Operating activities	$ 40.1	$ 40.7	$ (0.6)
Investing activities	12.8	58.1	(45.3)
Financing activities	(19.5)	7.5	(27.0)
Purchases of property, plant and equipment (included in investing activities above)	(10.8)	(7.8)	(3.0)

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, N.A., or Bank of America, described in Note 7 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 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 and for stock repurchase programs. Certain R&D costs may be funded under collaboration agreements with our collaboration partners.

Operating activities provided net cash of $40.1 million during the first quarter of 2011, primarily from net income of $23.3 million and non-cash charges to net income of $16.8 million. Non-cash charges primarily consisted of depreciation of $6.2 million, stock-based compensation expense of $6.0 million and amortization of intangibles of $5.2 million.

Net cash provided by investing activities during the first quarter of 2011 was $12.8 million. Cash provided during the first quarter of 2011 consisted primarily of $24.7 million in net proceeds from the sale and maturities of marketable securities, offset by purchases of property, plant and equipment of $10.8 million.

Net cash used in financing activities during the first quarter of 2011 was $19.5 million, primarily driven by $48.0 million used to repurchase and retire approximately 756,000 shares of our common stock under our 2011 stock repurchase program. This was offset by $17.4 million in proceeds from the issuance of our common stock under stock option and employee stock purchase plans and $10.0 million in additional borrowings under our credit facility.

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 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

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debt securities, any significant needs for cash may cause us to liquidate some or all of our marketable debt securities resulting in the need to partially or completely pay down, or refinance, this indebtedness.

Contractual Obligations

We borrowed an additional $10.0 million under our revolving credit facility during the first quarter of 2011. As a result, the total principal amount outstanding under our revolving credit facility was $250.0 million as of March 31, 2011.

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.

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 March 31, 2011, the total principal amount outstanding under the revolving credit facility was $250.0 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 $2.5 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 $2.0 million on an annual basis. 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

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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 (loss) 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 quarter of 2011, 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 $5.3 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 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 March 31, 2011 were not material. Our receivables by currency as of March 31, 2011 reflected in U.S. dollar equivalents were as follows (in millions):

U.S. dollar	$ 46.9
Euro	7.6
British pound	3.7
Canadian dollar	1.5
Czech koruna	0.2
Danish krone	0.1
Total gross trade accounts receivable	$ 60.0

Item 4. Controls and Procedures

We maintain disclosure controls and procedures 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, 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 Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were

effective as of March 31, 2011.

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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 did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 9 Contingencies, of the Notes to 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, 2010.

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 projections. We expect continuing fluctuations in our manufacture and shipment of blood screening products and instruments 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.

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

Our business depends on the overall demand for our products and on the economic health of our current and prospective customers. Our projected revenues and operating results are based on assumptions concerning certain levels of customer demand. 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 34% of our total product sales for the first three months of 2011 and 39% of our total product sales for 2010. 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 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 June 2010, for example, 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

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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, Siemens and Pacific Biosciences, 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 acquired 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 October 2009 we acquired Prodesse, which we believe supports our strategic focus on commercializing differentiated molecular tests for infectious diseases. In addition, in December 2010, we acquired GTI Diagnostics, which we believe will strengthen our transplant diagnostics business, and provide us access to the specialty coagulation and transfusion-related blood bank markets. 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 expectations, and could adversely affect our operating results.

Managing the acquisitions of Tepnel, Prodesse and GTI Diagnostics, 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;
- 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;

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

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 PANTHER instrument system, or our failure to modify existing assays or develop new assays for use with the 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, such as our APTIMA HPV and PROGENSA PCA3 assays, may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and these and other new products may not be successfully commercialized. Failure to timely achieve regulatory approval for our products and introduce products to market could negatively 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.

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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., One Lambda, Inc., 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 granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron also granted HIV and HCV licenses in the clinical diagnostics field to Bayer Healthcare LLC (now Siemens), together with the right to grant certain additional HIV and HCV sublicenses in the field to third parties. 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.

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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.

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; and Stratec Biomedical Systems AG, or Stratec, is the only manufacturer of our 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 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.

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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. In August 2010, the FDA s Center for Devices and Radiological Health, or CDRH, issued two reports outlining potential changes to the 510(k) regulatory process. In addition, in January 2011, the CDRH issued an implementation plan containing 25 specific actions to be implemented in 2011 relating to the 510(k) regulatory process and associated administrative matters. The CDRH also deferred action on several other initiatives, including the creation of a new class of devices that would be subject to heightened review processes, until the Institute of Medicine issues a related report on the 510(k) regulatory process, which is expected to be released in the summer of 2011. Many of the actions proposed by the CDRH could result in significant changes to the 510(k) process, which would likely complicate the process of getting products cleared by 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 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 addition, unexpected complications in conducting trials could cause us to incur unanticipated expenses or result in delays or difficulties in receiving FDA approval. For example, when we started the U.S. clinical trial for our investigational APTIMA HPV assay we originally expected that we would enroll and test approximately 7,000 women. However, we actually enrolled approximately 13,000 women in the trial based on the actual prevalence of cervical disease observed. Although we submitted a PMA to the FDA for our investigational APTIMA HPV assay on the TIGRIS system in the fourth quarter of 2010, we cannot provide any assurances that the FDA will ultimately approve the use of our APTIMA HPV assay. We have also recently submitted applications to the FDA for clearance or approval of a number of other assays, including our PROGENSA PCA3 assay. There can be no assurance that any of these assays will be approved for sale in the United States on a timeline consistent with our expectations, or at all. Failure to obtain or delay in obtaining FDA approval of any of our newly developed assays could have a material adverse effect on our financial performance.

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.

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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 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. In March 2011, we received a letter from the FDA classifying our December 2008 voluntary recall as a Class 1 recall, the most serious of the recall classifications used by the FDA.

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

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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 may 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 product sales, 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 product sales, and we do not have any long-term commitments with these customers, other than our collaboration agreement with Novartis. Product sales from our blood screening collaboration with Novartis accounted for 34% of our total product sales for the three months ended March 31, 2011 and 39% of our total product sales for 2010. Our blood screening collaboration with Novartis is largely dependent on three large customers in the United States, The American Red Cross, America s Blood Centers and Creative Testing Solutions, 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 both the first three months of 2011 and 2010. However, various state and city public health agencies accounted for an aggregate of 7% of our total revenues for both the first three months of 2011 and 2010. 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 550 U.S. and foreign patents covering our products and technologies as of March 31, 2011, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by 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

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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 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. 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 alleging 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 second complaint also 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 were informed that the Patent and Trademark Office determined that Institut Pasteur invented the subject matter at issue prior to NIH and Novartis. We were 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

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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 price increases, 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. Subject to the terms of the credit agreement, including the amount of funds that we are permitted to borrow from time to time under the credit agreement, 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. As of March 31, 2011, the total principal amount outstanding under the revolving credit facility was $250.0 million. The term of our credit facility with Bank of America has been extended twice and currently expires in February 2012.

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,

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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 March 31, 2011, we had approximately $521.3 million of long-lived assets, including $14.0 million of capitalized software, net of accumulated amortization, relating primarily to our TIGRIS and PANTHER instruments, goodwill of $150.6 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., and $182.1 million of capitalized licenses and manufacturing access fees, patents, purchased intangible assets and other long-term assets. Additionally, we had $69.2 million of land and buildings, $23.6 million of building improvements, $66.9 million of equipment and furniture and fixtures and $3.8 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 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 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.

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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 debt 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. In addition, the Pacific Biosciences common stock we hold, which trades on the NASDAQ Global Select Market under the symbol PACB , is also subject to various market and investment risks. We may lose all or a portion of the value of our investment in Pacific Biosciences as a result of a decline in the value of Pacific Biosciences common stock.

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.

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

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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 FDA requirements relating to the Quality System Regulation. 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 26% of our total revenues for the first three months of 2011 and 27% of our total revenues for 2010. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 53% of our total international revenues for the first three months of 2011 and 58% of our total international revenues for 2010.

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 international markets. 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. In addition, foreign medical reimbursement rules are not always consistent with

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U.S. approaches and often differ from country to country, which complicates the process of introducing new products in foreign jurisdictions.

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.

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 most of 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

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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 five manufacturing facilities, two of which are located in San Diego, California, two of which are located in Waukesha, Wisconsin and the other is located in Stamford, Connecticut. 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.

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 eruptions of a volcano in Iceland 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 or the earthquake and tsunami in Japan during March 2011. 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

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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, including as a result of acquisitions, has placed and may continue to place a significant strain on our personnel, facilities, management systems and resources. We need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce in order to effectively manage our growth. 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.

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.

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

The following table summarizes our common stock repurchase activity during the first quarter of 2011:

	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
January 1-31, 2011		$		$ 150,000,000
February 1-28, 2011	425,193	62.55	420,400	123,710,704
March 1-31, 2011	336,027	64.68	335,200	102,028,452
Total [1] [2]	761,220	$ 63.49	755,600	

[1] In February 2011, our Board of Directors authorized the repurchase of up to $150.0 million of our common stock until December 31, 2011, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the first quarter of 2011, we repurchased and retired approximately 756,000 shares under this program at an average price of $63.49 per share, or approximately $48.0 million in total. Our Board of Directors authorized a similar repurchase program of up to $100.0 million of our common stock in 2010, which was completed during the fourth quarter of 2010.

[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 first quarter of 2011, we repurchased and retired 5,620 shares of our common stock, at an average price of $63.76, 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.

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(6)	Amendment No. 3 to Credit Agreement dated as of February 10, 2011 by and between Gen-Probe Incorporated, as Borrower, and Bank of America, N.A., as Lender.
10.2 §	Gen-Probe 2011 Employee Bonus Plan.

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Exhibit Number	Description
10.3	Product Development Addendum for the Panther Instrument and Ultrio Elite Assay, dated as of March 11, 2011, by and between Gen-Probe Incorporated and Novartis Vaccines and Diagnostics, Inc.**
31.1	Certification dated May 4, 2011, 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 May 4, 2011, 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 May 4, 2011, 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 May 4, 2011, 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.

§ Indicates management contract or compensatory plan, contract or arrangement.

* 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.

(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.

(6) Incorporated by reference to Gen-Probe s Current Report on Form 8-K filed with the SEC on February 15, 2011.

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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: May 4, 2011

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

DATE: May 4, 2011

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