GEN PROBE INC
Form 10-Q
May 08, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
x Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2012
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 (State or other jurisdiction of incorporation or organization)	33-0044608 (I.R.S. Employer Identification Number)
10210 Genetic Center Drive, San Diego, CA (Address of Principal Executive Office) (858) 410-8000 (Registrant's telephone number, including area code)	92121-4362 (Zip 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 x No ¨
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 x No ¨
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 x		Accelerated filer ¨
Non-accelerated filer ¨	(Do not check if a smaller reporting company)	Smaller Reporting Company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x
As of April 25, 2012, 45,386,659 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, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets		
Cash and cash equivalents	$138,774	$87,021
Marketable securities	174,409	218,789
Trade accounts receivable, net of allowance for doubtful accounts of $293 and $320 as of March 31, 2012 and December 31, 2011, respectively	67,199	57,767
Accounts receivable—other	2,317	3,446
Inventories	81,331	77,886
Deferred income tax	8,707	8,188
Prepaid expenses	15,792	11,555
Other current assets	3,732	4,967
Total current assets	492,261	469,619
Marketable securities, net of current portion	88,101	62,237
Property, plant and equipment, net	180,270	176,081
Capitalized software, net	17,961	16,992
Patents, net	11,486	11,758
Goodwill	140,385	140,404
Purchased intangibles, net	104,553	106,619
License, manufacturing access fees and other assets, net	61,246	61,738
Total assets	$1,096,263	$1,045,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$14,260	$12,000
Accrued salaries and employee benefits	21,533	28,795
Other accrued expenses	17,584	12,846
Income tax payable	6,428	1,857
Short-term borrowings	248,000	248,000
Deferred revenue	1,413	1,238
Total current liabilities	309,218	304,736
Non-current income tax payable	10,044	10,019
Deferred income tax	19,283	19,283
Deferred revenue, net of current portion	3,644	3,237
Other long-term liabilities	7,910	7,831
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, 45,342,898 and 45,008,879 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively	5	5

Additional paid-in capital	43,954	23,650
Accumulated other comprehensive income (loss)	2,745	(313)
Retained earnings	699,460	677,000
Total stockholders' equity	746,164	700,342
Total liabilities and stockholders' equity	$1,096,263	$1,045,448

See accompanying notes to consolidated financial statements

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

	Three Months Ended March 31,	
	2012	2011
Revenues		
Product sales	$150,117	$138,112
Collaborative research revenue	1,351	3,568
Royalty and license revenue	1,914	1,358
Total revenues	153,382	143,038
Operating expenses		
Cost of product sales (excluding acquisition-related intangible amortization)	52,371	41,943
Acquisition-related intangible amortization	2,759	2,805
Research and development	28,586	28,963
Marketing and sales	19,045	16,522
General and administrative	18,954	18,153
Total operating expenses	121,715	108,386
Income from operations	31,667	34,652
Other income (expense)		
Investment and interest income	2,538	735
Interest expense	(543)	(503)
Other income, net	128	177
Total other income, net	2,123	409
Income before income tax	33,790	35,061
Income tax expense	11,330	11,784
Net income	$22,460	$23,277
Net income per share		
Basic	$0.50	$0.49
Diluted	$0.49	$0.48
Weighted average shares outstanding		
Basic	45,124	47,861
Diluted	46,204	49,004

See accompanying notes to consolidated financial statements

GEN-PROBE INCORPORATED
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2012	2011
Comprehensive income	$25,518	$22,422

See accompanying notes to consolidated financial statements

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

	Three Months Ended March 31,	
	2012	2011
Operating activities		
Net income	$22,460	$23,277
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization	11,448	11,345
Amortization of premiums on investments, net of accretion of discounts	2,037	2,673
Stock-based compensation	6,152	6,036
Excess tax benefit from employee stock-based compensation	(1,246)	(1,425)
Deferred revenue	477	97
Deferred income tax	(245)	(615)
Loss on disposal of property and equipment	52	24
Changes in assets and liabilities		
Trade and other accounts receivable	(8,117)	(2,816)
Inventories	(3,506)	3,420
Prepaid expenses	(4,062)	(2,116)
Other current assets	1,161	(536)
Other long-term assets	199	(132)
Accounts payable	2,228	(3,196)
Accrued salaries and employee benefits	(7,725)	(7,847)
Other accrued expenses	4,566	(40)
Income tax payable	5,902	11,500
Other long-term liabilities	(49)	456
Net cash provided by operating activities	31,732	40,105
Investing activities		
Proceeds from sales and maturities of marketable securities	144,227	30,460
Purchases of marketable securities	(127,119)	(5,731)
Purchases of property, plant and equipment	(9,265)	(10,762)
Purchases of capitalized software	(1,738)	(780)
Purchases of intangible assets, including licenses and manufacturing access fees	(825)	(923)
Other	408	501
Net cash provided by investing activities	5,688	12,765
Financing activities		
Repurchase and retirement of common stock	—	(47,972)
Proceeds from issuance of common stock and employee stock purchase plan shares	14,232	17,390
Repurchase and retirement of restricted stock for payment of taxes	(1,124)	(358)
Excess tax benefit from employee stock-based compensation	1,246	1,425
Borrowings	—	10,000
Net cash provided by (used in) financing activities	14,354	(19,515)
Effect of exchange rate changes on cash and cash equivalents	(21)	518
Net increase in cash and cash equivalents	51,753	33,873

Cash and cash equivalents at the beginning of period	87,021	59,690
Cash and cash equivalents at the end of period	$138,774	$93,563

See accompanying notes to consolidated financial statements

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Notes to 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") as of March 31, 2012, and for the three month periods ended March 31, 2012 and 2011, 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 interim 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, 2012.

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, 2011.

Principles of Consolidation

These unaudited interim 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 has not identified any interests in variable interest entities that require consolidation.

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported in the consolidated financial statements. These estimates include assessing the collectability of accounts receivable, the recognition of revenues, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; accrued liabilities; 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. Product sales by product line are presented in Note 10 of these Notes to Consolidated Financial Statements.

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, the consideration is fixed and determinable, and collection of the resulting receivable is reasonably assured.

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 customer acceptance. For certain customers with non-standard payment terms, instrument sales are recorded based upon expected cash collection. Prior to delivery, each instrument is tested to meet Gen-Probe's specifications and the specifications of the United States Food and Drug Administration (the "FDA"), 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 for its research products and services in the period during which the related costs are incurred or the 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.

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, if the arrangement includes a general right of return relative to the delivered items, and if delivery or performance of the undelivered items is considered probable and substantially within the Company's control. 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. When VSOE of fair value is not available, third-party evidence ("TPE") of fair value is acceptable, or a best estimate of the selling price if neither VSOE nor TPE is available. A best estimate of the 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 with stand-alone value are recognized at the time that the Company has satisfied all performance obligations. License fees without stand-alone value are recognized in combination with any undelivered 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 the Company's consolidated balance sheets.

Royalty and license revenue is recognized in connection with 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

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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"). Certain of these costs are capitalized into inventory on the Company's consolidated balance sheets, and are recognized as an expense when the related products are sold.

The Company uses the Black-Scholes-Merton option pricing model to value stock options granted. The determination of the fair value of stock option 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.

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.

The following table presents the weighted average assumptions used by the Company 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:

	Three Months Ended March 31,			
	2012		2011	
Stock options				
Risk-free interest rate	0.7	%	1.7	%
Volatility	34.5	%	31.0	%
Dividend yield	—		—	
Expected term (years)	4.3		4.3	
Resulting average fair value	$19.57		$17.46	
Performance stock awards				
Risk-free interest rate	0.4	%	1.3	%
Volatility	30.1	%	33.4	%
Dividend yield	—		—	
Resulting average fair value	$81.96		$82.58	
Employee stock purchase plan shares				
Risk-free interest rate	0.1	%	0.2	%

Volatility	38.7	%	21.5	%
Dividend yield	—		—	
Expected term (years)	0.5		0.5	
Resulting average fair value	$15.27		$12.27	

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company's unrecognized stock-based compensation expense as of March 31, 2012, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards was as follows (in thousands, except number of years):

	Weighted Average Remaining Expense Life (Years)	Unrecognized Expense
Stock options	3.0	$36,530
Performance stock awards	2.6	10,871
Restricted stock	1.8	1,907
Deferred issuance restricted stock	1.2	247
Employee stock purchase plan shares	0.2	118
Total		$49,673

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, 2012 and 2011 (in thousands):

	Three Months Ended March 31,	
	2012	2011
Cost of product sales	$850	$788
Research and development	1,724	1,792
Marketing and sales	731	612
General and administrative	2,847	2,844
Total	$6,152	$6,036

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, unrecognized stock-based compensation expense 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 1.4 million and 0.7 million shares for the three month periods ended March 31, 2012 and 2011, 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, 2012 and 2011 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2012	2011

Basic net income per share		
Net income	$22,460	$23,277
Less income allocated to participating securities	(30)	(35)
Net income allocated to common stockholders	$22,430	$23,242
Weighted average common shares outstanding - basic	45,124	47,861
Net income per share - basic	$0.50	$0.49

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Three Months Ended March 31,	
	2012	2011
Diluted net income per share		
Net income	$22,460	$23,277
Less income allocated to participating securities	(29)	—
Net income allocated to common stockholders	$22,431	$23,277
Weighted average common shares outstanding - basic	45,124	47,861
Dilutive securities	1,080	1,143
Weighted average common shares outstanding - diluted	46,204	49,004
Net income per share - diluted	$0.49	$0.48

Adoption of Recent Accounting Pronouncements

Accounting Standards Update 2011-04

In May 2011, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") on fair value measurement. The ASU expands the disclosure requirements of Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurement ("ASC Topic 820"), for fair value measurements and makes other amendments. Specifically, the ASU clarifies the accounting guidance for highest-and-best-use and valuation-premise concepts for non-financial assets, application to financial assets and financial liabilities with offsetting positions in market risks or counterparty credit risk, premiums or discounts in fair value measurement, and fair value of an instrument classified in an entity's stockholders' equity. Additionally, the ASU expands the disclosure requirements under ASC Topic 820, particularly for Level 3 inputs. The ASU was effective for interim and annual reporting periods of the Company beginning January 1, 2012. 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 2011-05 and 2011-12

In June 2011, the FASB issued ASU 2011-05 on the presentation of comprehensive income. The ASU removes the presentation options in ASC Topic 220, Comprehensive Income, and requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. The ASU does not change the items that must be reported in other comprehensive income (loss) and does not require any incremental disclosures in addition to those already required under existing accounting guidance. The ASU was effective for interim and annual reporting periods of the Company beginning January 1, 2012. For the three months ended March 31, 2012, the Company has applied the provisions of ASU 2011-05 by presenting comprehensive income in a statement separate from the consolidated statements of income.

In December 2011, the FASB issued ASU 2011-12, deferring certain provisions of ASU 2011-05. One of the provisions of ASU 2011-05 required entities to present reclassification adjustments out of accumulated other comprehensive income (loss) by component in both the statement in which net income is presented and the statement in which other comprehensive income (loss) is presented (for both interim and annual financial statements). This requirement is indefinitely deferred by ASU 2011-12 and will be further deliberated by the FASB at a future date. The effective date of ASU 2011-12 is the same as that for the unaffected provisions of ASU 2011-05.

Accounting Standards Update 2011-08

In September 2011, the FASB issued an ASU on performing goodwill impairment testing. The ASU amends the guidance in ASU Topic 350-20, Goodwill. Under the revised guidance, entities testing goodwill for impairment have the option of performing a qualitative assessment before calculating the fair value of the reporting unit (step 1 of the goodwill impairment test). If entities determine, on the basis of qualitative factors, that the fair value of the reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required. The ASU does not change how goodwill is calculated or assigned to reporting units, does not revise the requirement to test goodwill annually for impairment, and does not amend the requirement to test goodwill for impairment between annual tests if events and circumstances warrant. The ASU provides examples of events and circumstances to consider for qualitative assessment. The amendments were effective for annual and interim goodwill impairment tests performed by the Company beginning January 1, 2012. The Company adopted this guidance in the first quarter

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of 2012 for its goodwill impairment testing. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

Note 2. Restructuring Activities

Following its acquisition of Tepnel Life Sciences plc ("Tepnel") in April 2009, the Company had four locations in the United Kingdom ("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. The Company estimates that expenses related to this consolidation will total approximately $4.7 million and will be incurred in phases over a two-year period ending in the second quarter of 2012. 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 first quarter of 2012, the Company decided to restructure certain of its business activities relating to its acquired Genetic Testing Institute, Inc. ("GTI Diagnostics") business and the customer service functions for the U.S. portion of its Tepnel business. The restructuring is intended to optimize the operational efficiency and cost structure of the Company. The Company estimates that expenses relating to this restructuring will total $0.5 million and will be incurred within the first half of 2012. These expenses will include severance costs related to the elimination of certain positions and site closure costs relating to a facility outside of the U.S.

During the three months ended March 31, 2012, the Company recorded approximately $1.1 million of termination and site closure costs. These amounts are included in general and administrative expenses in the Company's consolidated statements of income. Through March 31, 2012, the Company has recorded approximately $4.9 million of cumulative termination and site closure costs related to these restructuring activities.

The following table summarizes the restructuring activities accounted for under ASC Topic 420 for the three months ended March 31, 2012, as well as the remaining restructuring accrual on the Company's consolidated balance sheets as of March 31, 2012 (in thousands):

	Termination Costs	Site Closure Costs	Total
Restructuring reserves as of December 31, 2011	$267	$440	$707
Charged to expenses	657	448	1,105
Amounts paid	(460)	(425)	(885)
Foreign currency translation	10	14	24
Restructuring reserves as of March 31, 2012	$474	$477	$951

Note 3. Balance Sheet Information

The following tables provide details of selected balance sheet line items as of March 31, 2012 and December 31, 2011 (in thousands):

Inventories

	March 31, 2012	December 31, 2011
Raw materials and supplies	$18,170	$19,429
Work in process	28,192	27,464
Finished goods	34,969	30,993
Inventories	$81,331	$77,886

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property, Plant and Equipment, Net

	March 31, 2012	December 31, 2011
Land	$19,369	$19,355
Building	79,809	80,005
Machinery and equipment	219,786	213,729
Building improvements	64,956	60,628
Furniture and fixtures	22,270	21,790
Construction in-progress	1,199	2,789
Property, plant and equipment, at cost	407,389	398,296
Less: accumulated depreciation and amortization	(227,119)	(222,215)
Property, plant and equipment, net	$180,270	$176,081

Purchased Intangibles

	March 31, 2012		December 31, 2011	
	Gross	Accumulated Amortization	Gross	Accumulated Amortization
Customer relationships	$77,720	$(17,447)	$77,326	$(15,723)
Developed technology	59,206	(38,855)	59,206	(38,292)
Trademarks	10,879	(1,631)	10,817	(1,487)
Trade names	7,300	(526)	7,300	(435)
In-process research and development	7,907	—	7,907	—
Total purchased intangibles	$163,012	$(58,459)	$162,556	$(55,937)

License, Manufacturing Access Fees and Other Assets, Net

	March 31, 2012	December 31, 2011
License and manufacturing access fees	$68,488	$67,906
Investment in Qualigen, Inc.	5,404	5,404
Investment in DiagnoCure, Inc.	5,000	5,000
Investment in Roka Bioscience, Inc.	4,705	4,705
Other assets	11,909	11,257
License, manufacturing access fees and other assets, at cost	95,506	94,272
Less: accumulated amortization	(34,260)	(32,534)
License, manufacturing access fees and other assets, net	$61,246	$61,738

Other Accrued Expenses

	March 31, 2012	December 31, 2011
Research and development	$5,431	$3,554
Professional fees	3,471	1,148
Royalties	2,778	3,047

Marketing and sales	1,754	1,261
Other	4,150	3,836
Other accrued expenses	$17,584	$12,846

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Marketable Securities

The Company's marketable securities include equity securities, mutual funds, treasury securities and tax advantaged municipal securities. The equity securities consist of investments in common stock. The deferred compensation plan assets are invested in mutual funds with quoted market prices. The Company's investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years with a minimum Moody's credit rating of A3 or a Standard & Poor's credit rating of A-. As of March 31, 2012, the Company's portfolio had an average maturity of three 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, 2012 and December 31, 2011 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
March 31, 2012				
Debt securities	$251,494	$487	$(677)	$251,304
Equity securities	10,518	688	—	11,206
Mutual funds	6,233	408	—	6,641
Total marketable securities	$268,245	$1,583	$(677)	$269,151
December 31, 2011				
Debt securities	$270,745	$1,298	$(191)	$271,852
Equity securities	10,518	—	(1,344)	9,174
Mutual funds	6,127	16	(88)	6,055
Total marketable securities	$287,390	$1,314	$(1,623)	$287,081

The following table shows the estimated fair values and gross unrealized losses as of March 31, 2012 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
$76,895	$(677)	$—	$—

As of March 31, 2012 and December 31, 2011, the Company had 22 and 18 marketable debt securities, respectively, in an unrealized loss position. Of the 22 debt securities in an unrealized loss position as of March 31, 2012, the average estimated fair value and average unrealized loss was $3.5 million and $31,000, respectively. Of the 18 debt securities in an unrealized loss position at December 31, 2011, the average estimated fair value and average unrealized loss was $2.9 million and $11,000, respectively.

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 as of March 31, 2012 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 Company periodically reviews its marketable equity securities for other-than-temporary declines in fair value below their cost basis, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. When assessing marketable equity securities for other-than-temporary declines in value, the Company considers factors including: the significance of the decline in value compared to the cost basis; the underlying factors contributing to a decline in the prices of securities in a single asset class; how long the market value of the investment has been less than its cost basis; any market conditions that impact liquidity; the views of external investment analysts; the financial condition and near-term prospects of the investee; any news or

financial information that has been released specific to the investee; and the outlook for the overall industry in which the investee operates.

The following table shows the current and non-current classification of the Company's marketable securities as of March 31, 2012 and December 31, 2011 (in thousands):

	March 31, 2012	December 31, 2011
Current	$174,409	$218,789
Non-current [1]	94,742	68,292
Total marketable securities	$269,151	$287,081

(1) Deferred compensation plan assets invested in mutual funds are included under the caption "License, manufacturing access fees and other assets, net" on the Company's consolidated balance sheets.

As of March 31, 2012, the Company held non-current marketable debt and equity securities of $76.9 million and $11.2 million, respectively, and non-current deferred compensation plan assets invested in mutual funds of $6.6 million. As of December 31, 2011, the Company held non-current marketable debt and equity securities of $53.0 million and $9.2 million, respectively, and non-current deferred compensation plan assets invested in mutual funds of $6.1 million. Investments in an unrealized loss position deemed to be temporary as of March 31, 2012 and December 31, 2011 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 and equity securities, other than mutual funds, 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 during the three month periods ended March 31, 2012 and 2011 (in thousands):

	Three Months Ended March 31,	
	2012	2011
Proceeds from sale of marketable securities	$146,184	$30,153
Gross realized gains	$1,957	$2
Gross realized losses	—	(356)
Net realized gain (loss)	$1,957	$(354)

Note 5. 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. Applicable accounting guidance under ASC

Topic 820 establishes three levels of inputs that may be used to measure fair value:

- 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.

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 cash equivalents and marketable securities include equity securities, mutual funds, treasury securities, tax advantaged municipal securities, and money market funds. When available, the Company uses quoted market prices to determine fair value and classifies such items as Level 1. The Company's Level 1 financial instruments include equity securities and mutual funds. The Company obtains the fair value of its Level 2 financial instruments from a professional pricing service, which may determine the fair value using quoted 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 validates the fair value of its Level 2 marketable debt securities provided by its professional pricing service by evaluating the reasonableness of the methods and assumptions used by the professional pricing service, and by comparing their assessment of the fair value of the Company's investment portfolio against the fair value of the Company's investment portfolio from an independent professional pricing source and with publicly available data for actual transactions.

The following tables present 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, 2012 and December 31, 2011 (in thousands):

	March 31, 2012 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 Sheets
Assets				
Cash equivalents	$—	$82,762	$—	$82,762
Marketable securities				
Equity securities	11,206	—	—	11,206
Municipal securities	—	251,304	—	251,304
Mutual funds	6,641	—	—	6,641
Total marketable securities	17,847	251,304	—	269,151
Total assets at fair value	$17,847	$334,066	$—	$351,913
Liabilities				
Deferred compensation plan liabilities	$6,641	$—	$—	$6,641

Total liabilities at fair value	$6,641	$—	$—	$6,641

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	December 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 Sheets
Assets				
Cash equivalents	$—	$28,364	$—	$28,364
Marketable securities				
Equity securities	9,174	—	—	9,174
Municipal securities	—	271,852	—	271,852
Mutual funds	6,055	—	—	6,055
Total marketable securities	15,229	271,852	—	287,081
Total assets at fair value	$15,229	$300,216	$—	$315,445
Liabilities				
Deferred compensation plan liabilities	$6,055	$—	$—	$6,055
Total liabilities at fair value	$6,055	$—	$—	$6,055

Activity Between and Within Levels of the Fair Value Hierarchy

The Company's policy is to record transfers of assets and liabilities between Level 1 and Level 2 at their fair values as of the end of each reporting period, consistent with the date of the determination of fair value. There were no transfers between levels during the first quarter of 2012. In the fourth quarter of 2011, the Company converted its deferred compensation plan assets into mutual funds traded in active markets with quoted market prices. Similarly, in the fourth quarter of 2011, the participants' selected investments were converted to investments based on mutual funds traded in active markets with quoted market prices. Liabilities under the deferred compensation plan are recorded at amounts due to participants, based on the fair value of the participants' selected investments. Therefore, for the year ended December 31, 2011, the Company transferred $6.1 million of both deferred compensation plan assets and deferred compensation plan liabilities, respectively, from Level 2 to Level 1.

For those financial instruments measured at fair value on a recurring and non-recurring basis with significant Level 3 inputs, there was no activity for the three months ended March 31, 2012.

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

Certain assets and liabilities, including cost method investments, are measured at fair value on a non-recurring basis and therefore are not included in the tables 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 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 had a value of $5.0 million as of March 31, 2012, 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.

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 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.

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. However, 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.

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. As of March 31, 2012, the Company owns shares of preferred stock representing approximately 14.7% of Roka's capital stock on a fully diluted basis. The Company's investment has been valued based on the transaction price under the cost basis of accounting. The Company's overall investment in Roka had a value of approximately $4.7 million as of March 31, 2012, and is included in "Licenses, manufacturing access fees and other assets, net" on the Company's consolidated balance sheets.

Qualigen, Inc.

The Company invested in Qualigen, Inc. ("Qualigen"), a private company, in 2006. The Company's investment in Qualigen, which had a value of approximately $5.4 million as of March 31, 2012, has been valued based upon several factors, including a market approach and an income (discounted cash flow) approach. This investment is also included in "Licenses, manufacturing access fees and other assets, net" on the Company's consolidated balance sheets.

Note 6. 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 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 March 2009, the Company and Bank of America amended the credit agreement to increase the amount that the Company may 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 three times and currently expires in February 2013. In June 2011, Bank of America issued a £1.2 million standby letter of credit on behalf of the Company, thereby reducing the amount the Company can borrow under the credit facility by the face amount of the letter of credit. The total principal amount outstanding under the revolving credit

facility as of March 31, 2012 was $248.0 million, the interest rate payable on such outstanding amount was approximately 0.84% and no further borrowings are currently available under the credit facility.

Note 7. Income Tax

As of March 31, 2012, the Company had total gross unrecognized tax benefits of $13.0 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 $10.0 million. The Company's federal tax returns for the 2008 through 2010 tax years, California tax returns for the 2005 through 2010 tax years, and UK tax returns for the 2008 through 2010 tax years are subject to future examination.

Note 8. Contingencies

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.

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 the Company's 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.

Enzo Life Sciences, Inc.

In January 2012, Enzo Life Sciences, Inc. ("Enzo") filed a patent infringement action against the Company in the United States District Court for the District of Delaware. The complaint alleges that the Company's manufacture and sale of certain molecular diagnostic assays, including the APTIMA Combo 2 and APTIMA HPV assays, that incorporate the Company's patented hybridization protection assay technology infringe Enzo's U.S. patent number 6,992,180. The complaint seeks monetary damages and injunctive relief. The Company intends to vigorously defend the lawsuit. There can be no assurances as to the final outcome of this litigation. The Company has not recorded an accrual as of

March 31, 2012 for a contingent liability associated with this legal proceeding based on the Company's belief that any liability is neither probable nor reasonably possible. In addition, any possible loss or range of loss cannot be reasonably estimated at this time.

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity

Changes in stockholders' equity for the three months ended March 31, 2012 were as follows (in thousands):

Balance as of December 31, 2011	$700,342
Net income	22,460
Other comprehensive income, net	3,058
Proceeds from the issuance of common stock and ESPP shares	14,232
Issuance of common stock to board members	71
Repurchase and retirement of restricted stock for payment of taxes	(1,124)
Stock-based compensation	6,104
Stock-based compensation income tax benefits	1,021
Balance as of March 31, 2012	$746,164

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, 2012 and 2011 were as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
Net income, as reported	$22,460	$23,277
Other comprehensive income (loss)		
Foreign currency translation adjustment	1,788	2,328
Unrealized gains (losses)		
Change in net unrealized gain (loss) on available-for-sale securities during the period	2,542	(3,413)
Realized (gain) loss on available-for-sale securities, net of tax	(1,272)	230
Total unrealized gains (losses)	1,270	(3,183)
Total other comprehensive income (loss), net	3,058	(855)
Comprehensive income	$25,518	$22,422

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GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Options

A summary of the Company's stock option activity for all equity incentive plans for the three months ended March 31, 2012 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 as of December 31, 2011	5,513	$50.80		
Granted	767	68.39		
Exercised	(316)	45.09		
Cancelled	(35)	59.00		
Outstanding as of March 31, 2012	5,929	$53.33	4.1	$80,823
Exercisable as of March 31, 2012	3,737	$49.97	3.1	$62,235

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, 2012 is as follows (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2011	62	$54.35
Granted	3	61.86
Vested	(3)	51.17
Forfeited	(1)	53.26
Unvested as of March 31, 2012	61	$54.82

Performance Stock Awards

A summary of the Company's performance stock award activity for the three months ended March 31, 2012 is as follows (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2011	109	$73.92
Awarded	108	82.00
Vested and issued	(46)	72.33
Cancelled	(1)	72.63
Unvested as of March 31, 2012	170	$79.46

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.

GEN-PROBE INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. 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, 2012 and 2011 were as follows (in thousands):

	Three Months Ended March 31,					
	2012			2011		
	$	%		$	%	
Clinical diagnostics	$94,919	63	%	$88,290	64	%
Blood screening	52,543	35	%	46,705	34	%
Research products and services	2,655	2	%	3,117	2	%
Total product sales	$150,117	100	%	$138,112	100	%

During the three month periods ended March 31, 2012 and 2011, 36% and 35%, respectively, of the Company's 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, 2012 and 2011.

Note 11. Subsequent Event

Entry into Agreement and Plan of Merger with Hologic, Inc.

On April 29, 2012, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Hologic, Inc. ("Hologic") and Gold Acquisition Corp., a wholly owned subsidiary of Hologic ("Merger Sub"), pursuant to which Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and as a wholly owned subsidiary of Hologic (the "Merger"). Upon the effective time of the Merger, each outstanding share of the Company's common stock (other than shares held by any stockholders who are entitled to and who properly exercise appraisal rights under Delaware law, treasury shares, and shares held by the Company, Hologic, Merger Sub or any of their respective subsidiaries) will be canceled and converted into the right to receive $82.75 in cash, without interest, on the terms and subject to the conditions set forth in the Merger Agreement. Consummation of the Merger is subject to various conditions, including, among others, adoption of the Merger Agreement by the stockholders of the Company, and the termination or expiration of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and under any similar foreign statutes and regulations applicable to the Merger. The Company expects the Merger to close in the second half of 2012.

The Merger Agreement contains certain termination rights for each of Hologic and the Company, and if the Merger Agreement is terminated under certain circumstances, the Company may be required to pay Hologic a termination fee of $128.0 million or reimburse Hologic for its reasonable and documented out-of-pocket transaction-related expenses in an amount up to $20.0 million. Under certain circumstances specified in the Merger Agreement relating to Hologic's failure to secure adequate financing for the Merger, Hologic is required to pay the Company a financing failure fee of $200.0 million.

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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," "could," "would," "continue," "seeks" or "anticipates," or other similar words (including their use in the negative), or by discussions of future matters, such as our ability to complete the proposed merger transaction with Hologic, Inc. pursuant to the definitive agreement and plan of merger between the parties, the ability to satisfy the conditions to closing the merger transaction, including obtaining the required approval of our stockholders and necessary regulatory clearances or approvals, and the ability to recognize the anticipated benefits of the merger transaction, 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, 2012 unaudited interim consolidated 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, 2011 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, 2011. 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, 2011.

Some totals included in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and elsewhere in this Quarterly Report may not foot due to rounding.

Overview

Gen-Probe Incorporated (NASDAQ: GPRO) is 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, or IVD, 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, certain high-risk strains of the human papillomavirus, or HPV, and Trichomonas vaginalis, the parasite that causes trichomoniasis.

In recent years, we have expanded our portfolio of products with acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel Life Sciences plc, or Tepnel, in April 2009, offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse, Inc., or Prodesse, in October 2009 added a portfolio of real-time polymerase chain reaction, or PCR, products for detecting influenza and other infectious organisms. In addition, in December 2010 we acquired Genetic Testing Institute, Inc., or GTI Diagnostics, a manufacturer of certain of our transplant diagnostic products, as well as specialty coagulation and transfusion-related

blood bank products.

In blood screening, we developed and manufacture the PROCLEIX family of 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. These blood screening products are marketed worldwide by our blood screening collaborator, Novartis Vaccines and Diagnostics, Inc., or Novartis, under Novartis' trademarks. We were awarded a 2004 National Medal of Technology, the nation's highest honor for technological innovation, in recognition of our pioneering work in developing NAT systems to safeguard the blood supply in the United States.

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 commercializing our next-generation PANTHER instrument, which is a versatile, fully automated NAT system for low- to mid-volume laboratories. The PANTHER instrument was CE-marked and launched in Europe for diagnostic use in the fourth quarter

of 2010. In addition, in May 2011 we filed a 510(k) application with the United States Food and Drug Administration, or FDA, for clearance of our PANTHER system to run our APTIMA Combo 2 assay for the detection of chlamydia and gonorrhea. In August 2011, Health Canada granted us a medical device license to use the PANTHER system to run our APTIMA Combo 2 assay in Canada. We are also developing the PANTHER system for use in the blood screening market as part of our blood screening collaboration with Novartis.

Our development pipeline includes products to detect:
- certain genotypes of HPV, which can cause cervical cancer;
- gene-based markers for prostate cancer;
- the quantity of certain viruses, often referred to as the “viral load”;
- certain gastrointestinal pathogens;
- antigens and antibodies that are used to determine transplant and transfusion compatibility; and
- coagulation disorders.

Recent Events

Entry into Agreement and Plan of Merger with Hologic

On April 29, 2012, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Hologic, Inc., or Hologic, and Gold Acquisition Corp., a wholly-owned subsidiary of Hologic, or Merger Sub, pursuant to which Merger Sub will merge with and into us, and we will continue as the surviving corporation in the merger and as a wholly owned subsidiary of Hologic, which we refer to as the Merger.

At the effective time of the Merger, each outstanding share of our common stock (other than shares held by any stockholders who are entitled to and who properly exercise appraisal rights under Delaware law, treasury shares, and shares of common stock held by us, Hologic, Merger Sub or any of their respective subsidiaries) will be canceled and converted into the right to receive $82.75 in cash, without interest, on the terms and subject to the conditions set forth in the Merger Agreement.

We made customary representations and warranties and covenants in the Merger Agreement, including, among others, to cause a meeting of our stockholders to be held to consider the adoption of the Merger Agreement, and to observe certain limits on the conduct of our business between the date of the Merger Agreement and the consummation of the Merger. Consummation of the Merger is subject to customary closing conditions, including adoption of the Merger Agreement by our stockholders, and the termination or expiration of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and under any similar foreign statutes and regulations applicable to the Merger. We expect the Merger to close in the second half of 2012.

The Merger Agreement contains certain termination rights in favor of each of Hologic and us. Upon the termination of the Merger Agreement under certain circumstances, we are required to pay Hologic a termination fee of $128.0 million or reimburse Hologic for its reasonable and documented out-of-pocket transaction-related expenses in an amount up to $20.0 million.

To support its obligations under the Merger Agreement, Hologic has obtained debt financing commitments from Goldman Sachs Bank USA and Goldman Sachs Lending Partners LLC. Under certain circumstances specified in the Merger Agreement relating to Hologic’s failure to secure adequate financing for the Merger, Hologic is required to pay us a financing failure fee of $200.0 million.

Our board of directors unanimously approved the Merger Agreement following the unanimous recommendation of a strategic transaction committee of our board of directors.

Certain terms of the Merger Agreement and the Merger are summarized in, and the Merger Agreement has been filed as an exhibit to, the Current Report on Form 8-K we filed with the Securities and Exchange Commission on May 1, 2012.

Financial Results

Product sales for the first quarter of 2012 were $150.1 million, compared to $138.1 million in the same period of the prior year, an increase of 9%. Total revenues for the first quarter of 2012 were $153.4 million, compared to $143.0 million in the same

period of the prior year, an increase of 7%. Net income for the first quarter of 2012 was $22.5 million ($0.49 per diluted share), compared to net income of $23.3 million ($0.48 per diluted share) in the same period of the prior year, an increase of 2% on a per diluted share basis.

FDA Clearance of APTIMA Trichomonas Assay

In April 2011, the FDA cleared our APTIMA Trichomonas vaginalis assay for sale and marketing in the United States. The APTIMA Trichomonas assay is an amplified NAT that detects Trichomonas vaginalis, the most common curable sexually transmitted infection in the United States. The APTIMA Trichomonas assay has been approved for use on our fully automated, high-throughput TIGRIS instrument system.

FDA Approval of APTIMA HPV Assay

In October 2011, the FDA approved our APTIMA HPV assay, an amplified NAT that detects high-risk strains of HPV that are associated with cervical cancer and precancerous lesions, for sale and marketing in the United States. The APTIMA HPV assay has been approved to run on our TIGRIS instrument system.

FDA Approval of PROGENSA PCA3 Assay

In February 2012, the FDA approved our PROGENSA PCA3 assay, a prostate-cancer specific molecular diagnostic test, for sale and marketing in the United States. The PROGENSA PCA3 assay has been approved for use on our semi-automated Direct Tube Sampling, or DTS, instrument systems.

Stock Repurchase Programs

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 was no minimum or maximum number of shares to be repurchased under the program. We completed the program in August 2011, repurchasing and retiring approximately 2.5 million shares at an average price of $60.00 per share, or approximately $150.0 million in total.

In September 2011, our Board of Directors authorized the repurchase of up to an additional $100.0 million of our common stock from November 2011 through June 2012, through negotiated or open market transactions. There was no minimum or maximum number of shares to be repurchased under the program. We completed the program in December 2011, repurchasing and retiring approximately 1.7 million shares at an average price of $58.83 per share, or approximately $100.0 million in total.

The Merger Agreement we entered into with Hologic on April 29, 2012 does not allow us to repurchase additional shares of our common stock, subject to certain limited exceptions set forth in the Merger Agreement.

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 our assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

We believe there have been no significant changes during the first quarter of 2012 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, 2011.

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 Quarterly Report.

Results of Operations

Product Sales

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Clinical diagnostics	$94.9	$88.3	$6.6	7 %
Blood screening	52.5	46.7	5.8	12 %
Research products and services	2.7	3.1	(0.4)	(13)%
Total product sales	$150.1	$138.1	$12.0	9 %
As a percent of total revenues	98 %	97 %		

Our primary source of revenue comes from product sales, which consist primarily of the sale of clinical diagnostics and blood screening products. Our clinical diagnostic product sales consist primarily of the sale of our women's health, 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 Novartis' 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 9% during the first quarter of 2012 as compared to the same period in the prior year. The increase was primarily attributed to higher sales from APTIMA assays and instrumentation, and higher blood screening revenues.

Clinical Diagnostic Product Sales

Clinical diagnostic product sales, including assay, instrument, and ancillary sales, represented $94.9 million, or 63% of product sales during the first quarter of 2012, compared to $88.3 million, or 64% of product sales during the same period of the prior year. The $6.6 million increase was primarily attributed to increased sales of APTIMA assays and instruments. The increase was partially offset by lower sales of other infectious disease products.

During the first quarter of 2012, clinical diagnostic product sales were negatively affected by unfavorable estimated exchange rate impacts of $0.5 million as compared to the prior year, primarily due to a stronger U.S. dollar versus the Euro.

Blood Screening Product Sales

Blood screening product sales, including assay, instrument, and ancillary sales, represented $52.5 million, or 35% of product sales during the first quarter of 2012, compared to $46.7 million, or 34% of product sales during the same period of the prior year. The $5.8 million increase was attributed to increased sales of blood screening-related instrumentation and assays to Novartis.

During the first quarter of 2012, blood screening product sales were negatively affected by unfavorable estimated exchange rate impacts of $0.1 million as compared to the prior year, primarily due to a stronger U.S. dollar versus the Euro.

Research Products and Services

As a result of our acquisition of Tepnel in April 2009, we have established an additional category of product sales, which we refer to as “Research products and services.” These sales represent outsourcing services for the pharmaceutical, biotechnology

and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies. Research products and services revenues were $2.7 million during the first quarter of 2012 compared to $3.1 million during the same period of the prior year. The $0.4 million decrease was primarily due to continued market weakness affecting contract research organizations.

Collaborative Research Revenue

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Collaborative research revenue	$1.4	$3.6	$(2.2)	(61)%
As a percent of total revenues	1%	3%		

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. 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.

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 decreased 61% during the first quarter of 2012 compared to the same period of the prior year. The $2.2 million decrease was primarily due to decreased reimbursements received from Novartis for shared development expenses attributable to the development of the PANTHER instrument and related 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 the results that will 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 activities.

Royalty and License Revenue

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Royalty and license revenue	$1.9	$1.4	$0.5	36%
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 with stand-alone value are recognized at the time that we have satisfied all performance obligations. License fees without stand-alone value are recognized in combination with any undelivered performance obligations.

Royalty and license revenue increased by 36% during the first quarter of 2012 compared to the same period of the prior year. The $0.5 million increase was primarily attributable to an increase in 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,				
	2012	2011	$ Change	% Change	
Cost of product sales	$52.4	$41.9	$10.5	25	%
Gross profit margin as a percent of product sales	65 %	70 %			

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 increased 25% during the first quarter of 2012 compared to the same period of the prior year. The $10.5 million increase was primarily due to additional cost of sales related to higher sales from our APTIMA products, instruments and blood screening shipments to Novartis.

Our gross profit margin as a percentage of product sales decreased to 65% during the first quarter of 2012 from 70% during the same period of the prior year. The decrease in gross profit margin as a percentage of product sales was principally attributed to increased sales of lower margin instrumentation and lower sales of higher margin infectious disease products.

A portion of our blood screening revenues is attributable to sales of TIGRIS and PANTHER instruments to Novartis, which totaled $3.3 million and $2.0 million during the first quarter of 2012 and 2011, respectively. Under our collaboration agreement with Novartis, we sell instruments to Novartis at prices that approximate cost and share in profits of end-user sales in the United States. These instrument sales, therefore, negatively impact our gross margin percentage in the periods during which they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

Acquisition-related Intangible Amortization

(Dollars in millions)	Three Months Ended March 31,				
	2012	2011	$ Change	% Change	
Acquisition-related intangible amortization	$2.8	$2.8	$—	—	%
As a percent of total revenues	2 %	2 %			

Amortization expense related to our acquired intangible assets during the first quarter of 2012 was consistent with the same period of the prior year. 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,

	2012	2011	$ Change	% Change
Research and development	$28.6	$29.0	$(0.4)	(1)%
As a percent of total revenues	19%	20%		

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 1% during the first quarter of 2012 compared to the same period of the prior year. The $0.4 million decrease was primarily related to the reduction in development expenses as a result of the wind-down of the clinical trials for our HPV assay and lower development costs relating to our PANTHER instrument. These decreases were offset by increases in R&D expense relating to instrument development and virology programs. We have expanded our instrument development programs to include the addition of real-time PCR capabilities for the next-generation PANTHER system, and to develop a new instrument to further automate molecular testing from liquid-based cytology specimens.

Marketing and Sales

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Marketing and sales	$19.0	$16.5	$2.5	15 %
As a percent of total revenues	12 %	12 %		

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

Marketing and sales expenses increased 15% during the first quarter of 2012 compared to the same period of the prior year. The $2.5 million increase was primarily attributed to increases in headcount and personnel-related expenses attributable to our women’s health business and other marketing activities.

General and Administrative

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
General and administrative	$19.0	$18.2	$0.8	4 %
As a percent of total revenues	12 %	13 %		

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

G&A expenses increased 4% during the first quarter of 2012 compared to the same period of the prior year. The $0.8 million increase is primarily attributable to higher G&A costs relating to litigation and other professional services, and costs associated with our internal restructuring activities.

Total Other Income, Net

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Investment and interest income	$2.5	$0.7	$1.8	257 %
Interest expense	(0.5)	(0.5)	—	— %
Other income, net	0.1	0.2	(0.1)	(50)%
Total other income, net	$2.1	$0.4	$1.7	425 %

Investment and Interest Income

The $1.8 million increase in investment and interest income during the first quarter of 2012 compared to the same period of the prior year is primarily attributed to higher net realized gains on sales of marketable securities, partially offset by decreased interest income from lower investment balances during the first quarter of 2012 as a result of the sale of investments during 2011 to fund our stock repurchase programs.

Interest Expense

Interest expense was consistent, totaling $0.5 million during each of the first quarters of 2012 and 2011.

Other Income (Expense), Net

Other income (expense), net decreased by $0.1 million during the first quarter of 2012 compared to the same period of the prior year, primarily related to unfavorable exchange rate impacts.

Income Tax Expense

(Dollars in millions)	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Income tax expense	$11.3	$11.8	$(0.5)	(4)%
As a percent of income before income tax	34%	34%		

Our income tax expense decreased 4% during the first quarter of 2012 compared to the same period of the prior year. The $0.5 million decrease was attributable to lower 2012 pre-tax earnings.

Liquidity and Capital Resources

(Dollars in millions)	March 31, 2012	December 31, 2011
Cash, cash equivalents and current marketable securities	$313.2	$305.8
Working capital	$183.0	$164.9
Current ratio	1.6:1	1.5:1

Our working capital as of March 31, 2012 increased $18.1 million from December 31, 2011. This increase in working capital during the first quarter of 2012 was primarily attributable to increases in our trade accounts receivable, prepaid expenses and inventories, which totaled $9.4 million, $4.2 million and $3.4 million, respectively.

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 issuer.

Our marketable securities include equity securities, mutual funds, treasury securities and tax advantaged municipal securities. Our investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years with a minimum Moody’s credit rating of A3 or a Standard & Poor’s credit rating of A-. As of March 31, 2012, our portfolios had an average maturity of three years and an average credit quality of AA1 as defined by Moody’s.

(Dollars in millions)	Three Months Ended March 31,		
	2012	2011	$ Change
Cash provided by (used in):			
Operating activities	$31.7	$40.1	$(8.4)
Investing activities	5.7	12.8	(7.1)
Financing activities	14.4	(19.5)	33.9
Purchases of property, plant and equipment (included in investing activities above)	(9.3)	(10.8)	1.5

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 6 — Borrowings, of the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report. The term of our credit facility currently expires in February 2013. Our primary short-term cash needs, which are subject to change, include continued R&D expense 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 $31.7 million during the first quarter of 2012, primarily from net income of $22.5 million and non-cash charges to net income of $18.7 million, offset by a net increase in operating assets and liabilities of $9.4 million. Non-cash charges primarily consisted of stock-based compensation expense of $6.2 million, depreciation of $6.1 million and amortization of intangible assets of $5.3 million. The net increase in operating assets and liabilities of $9.4 million was primarily due to higher trade accounts receivable balances at the end of the first quarter of 2012 as a result of the timing of our cash collections from our product sales. The $8.4 million decrease in cash from operating activities during the first quarter of 2012 compared to the same period of the prior year was primarily due to increases in our inventory and trade receivables balances during the first quarter of 2012, partially offset by a larger increase in our income tax payable during the first quarter of 2011.

Net cash provided by investing activities during the first quarter of 2012 was $5.7 million. We received $17.1 million in net proceeds from the sales and maturities of marketable securities, which was partially offset by purchases of property, plant and equipment of $9.3 million, purchases of capitalized software of $1.7 million and purchases of intangible assets, including license fees of $0.8 million. The $7.1 million decrease in cash from investing activities during the first quarter of 2012 compared to the same period of the prior year was primarily due to $7.6 million of higher net proceeds in 2011 from the sales and maturities of our marketable securities.

Net cash provided by financing activities during the first quarter of 2012 was $14.4 million, primarily driven by $14.2 million in proceeds from the issuance of common stock under our equity incentive and employee stock purchase plans. The $33.9 million increase in cash from financing activities during the first quarter of 2012 compared to the same period of the prior year was primarily due to $48.0 million spent during the first quarter of 2011 to repurchase shares of our common stock under our stock repurchase program offset by $10.0 million of additional borrowings made in the first quarter of 2011 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 revolving 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, or at all. Further, debt financing may subject us to covenants restricting our operations. Because our current credit facility is secured by our marketable 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 did not enter into any material contractual obligations during the three months ended March 31, 2012. We have no material contractual obligations that are not fully recorded on our consolidated balance sheets or fully disclosed in the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report.

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 the 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, 2012, the total principal amount outstanding under the revolving credit facility was $248.0 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) the London Interbank Offered Rate, or 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 $1.6 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 the fair value of the investment is determined to be other-than-temporary.

Equity Price Risk

In connection with a collaboration agreement we entered into with Pacific Biosciences of California, Inc., or Pacific Biosciences, in June 2010, we purchased $50.0 million of Pacific Biosciences' Series F preferred stock as a participant in Pacific Biosciences' Series F preferred stock round of financing, which raised a total of approximately $109.0 million. In October 2010, Pacific Biosciences completed an initial public offering of its common stock at a price of $16.00 per share, and the stock now trades on the NASDAQ Global Select Market under the symbol "PACB." As a result of the initial public offering, our Pacific Biosciences' preferred stock was converted into common stock.

Our investment in Pacific Biosciences is subject to market price volatility. Fluctuations in the market price of publicly traded securities may result from perceived changes in the underlying economic characteristics of the issuer, the relative price of alternative investments, general market conditions and other factors.

We originally recorded our $50.0 million investment in Pacific Biosciences' preferred stock on a cost basis in our consolidated financial statements. Since Pacific Biosciences completed its initial public offering, our investment in Pacific Biosciences has been marked to fair market value each reporting period. We periodically review our marketable equity securities for other-than-temporary declines in fair value below their cost basis, or whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. In the third quarter of 2011, we recorded a $39.5 million other-than-temporary impairment, or OTTI, loss on our investment in Pacific Biosciences. As of March 31, 2012, our investment in Pacific Biosciences had a market value of $11.2 million.

A 10% percent increase or decrease in the fair value of our investment in Pacific Biosciences would result in an increase or decrease to the fair value of our investment of approximately $1.1 million. Because the market price for our investment in Pacific Biosciences is subject to ongoing fluctuation, the amount we may eventually realize from a subsequent sale of our investment may differ significantly from the reported market value.

Foreign Currency Exchange Risk

Although the majority of our revenue is realized in U.S. dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. We translate the financial statements of our non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates in intercompany

receivables and payables of a long-term investment nature are recorded as a separate component of stockholders' equity under the caption "Accumulated other comprehensive income (loss)." 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 three months of 2012, a 10% increase or decrease of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.0 million annually. Similarly, a 10% increase or decrease of currency exchange rates would result in a clinical diagnostic product sales increase or decrease of approximately $7.2 million annually. A 10% movement of currency exchange rates would result in a research products and services sales increase or decrease of approximately $1.1 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 accounts payable denominated in foreign currencies as of March 31, 2012 were not material. Our trade accounts receivable by currency as of March 31, 2012 reflected in U.S. dollar equivalents were as follows (in millions):

U.S. dollar	$52.7
Euro	6.9
British pound	4.4
Canadian dollar	2.2
Other	1.3
Total gross trade accounts receivable	$67.5

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, 2012.

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 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 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

We are a party to the following litigation and may also be involved in other legal proceedings arising in the ordinary course of business from time to time. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters 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.

Becton, Dickinson and Company

In October 2009, we filed a patent infringement action against Becton, Dickinson and Company, or BD, in the United States 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 United States 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.

Enzo Life Sciences, Inc.

In January 2012, Enzo Life Sciences, Inc., or Enzo, filed a patent infringement action against us in the United States District Court for the District of Delaware. The complaint alleges that our manufacture and sale of certain molecular diagnostic assays, including the APTIMA Combo 2 and APTIMA HPV assays, that incorporate our patented hybridization protection assay technology infringe Enzo's U.S. patent number 6,992,180. The complaint seeks monetary damages and injunctive relief. We intend to vigorously defend the lawsuit. There can be no assurances as to the final outcome of this litigation.

Putative Shareholder Class Action Litigation

In the days following the announcement that we had entered into the Merger Agreement with Hologic and Merger Sub, purported stockholders of the company filed two lawsuits in connection with the proposed transaction, the first lawsuit, captioned Teamsters Local Union No. 727 Pension Fund v. Gen-Probe Incorporated, et al., was filed in the Superior Court of the State of California for the County of San Diego against us, our directors and Hologic, and the second lawsuit, captioned Timothy Coyne v. Gen-Probe Incorporated, et al., or the Delaware Action, was filed in the Delaware Court of Chancery against us, our directors, Hologic and Merger Sub. Both actions were brought as putative class actions and allege that our directors breached certain alleged fiduciary duties to our stockholders by approving the Merger Agreement, and that Hologic and/or Merger Sub aided and abetted those breaches. The complaints request an injunction of the transaction. The Delaware Action also seeks damages in the event the transaction is completed. We believe that each of these actions is without merit.

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 our actual results to differ materially from the results contemplated by the forward-looking statements contained in this Quarterly 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, 2011.

Our business and results of operations may be affected by the announcement of our proposed acquisition by Hologic.*

On April 29, 2012, we entered into the Merger Agreement with Hologic and Merger Sub, pursuant to which Merger Sub will merge with and into us, and we will continue as the surviving corporation and as a wholly owned subsidiary of Hologic. The terms of the Merger Agreement and the Merger are described in more detail in Item 2 of Part I of this Quarterly Report on Form 10-Q.

The Merger could have an adverse effect on our revenue in the near term if customers delay, defer, or cancel purchases until the completion of the Merger. While we are attempting to mitigate this risk through communications with our customers, current and prospective customers could be reluctant to purchase our products and/or services due to potential uncertainty about the direction of our product offerings and our support and service of existing products. To the extent that the Merger creates uncertainty among customers or our employees such that any significant number of customers delay purchase decisions pending completion of the Merger, or our employees depart the company or become distracted, our results of operations and ability to operate profitably could be negatively affected. Decreased revenue or a failure to be profitable could have a variety of adverse effects, including negative consequences to our relationships with, and ongoing obligations to, customers, suppliers, employees, business partners, and others with whom we have business relationships. In addition, our quarterly operating results could fail to meet the expectations of market analysts, which could cause our stock price to decline.

We are also subject to additional risks in connection with the Merger, including: (1) the occurrence of an event or circumstance that could give rise to the payment of a termination fee by us of $128.0 million or the payment of Hologic's out-of-pocket transaction-related expenses in an amount up to $20.0 million, in each case pursuant to and in accordance with the terms of the Merger Agreement, (2) the outcome of any legal proceedings that may be instituted against us, our directors and others relating to the transactions contemplated by the Merger Agreement, (3) the failure of the Merger to close for any reason, including due to the failure to obtain the necessary regulatory approvals or Hologic's inability to secure adequate financing, (4) the restrictions imposed on our business, properties and operations pursuant to the affirmative and negative covenants set forth in the Merger Agreement and the potential impact of such covenants on our business, (5) the risk that the Merger will divert management's attention resulting in a potential disruption of our current business plan, and (6) potential difficulties in employee retention arising from the Merger.

We may suffer additional consequences if the proposed acquisition by Hologic is not completed.*

If the Merger is not completed, we could suffer a number of consequences that may adversely affect our business, results of operations and stock price, including the following:

- activities relating to the Merger and related uncertainties may divert our management's attention from our day-to-day business and cause disruptions among our employees and to our relationships with customers and business partners, thus detracting from our ability to grow revenue and possibly leading to a loss of revenue and market position that we may not be able to regain if the Merger does not occur;

- the market price of our common stock could decline following an announcement that the Merger has been abandoned, to the extent that the current market price reflects a market assumption that the Merger will be completed;

- if the Merger Agreement is terminated under certain circumstances, we may be required to pay a termination fee to Hologic or reimburse Hologic for its transaction-related expenses;

- if Hologic fails to secure adequate financing for the Merger, our remedies will be limited to receipt of a financing failure fee of $200.0 million;

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certain costs related to the Merger, including the fees and/or expenses of our legal, accounting and financial advisors, must be paid even if the Merger is not completed;

- we may be subject to legal proceedings related to the Merger;
- we may be the subject of other acquisition proposals that require management attention and that may be less favorable to us and our stockholders than the Merger;
- we may not be able to take advantage of alternative business opportunities or effectively respond to competitive pressures; and
- a failed transaction may result in negative publicity and/or a negative impression of us in the investment community

or business community generally.

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 or inventory levels for blood screening tests and instrumentation 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, including our APTIMA Trichomonas vaginalis, APTIMA HPV and PROGENSA PCA3 assays, 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 and year-over-year fluctuations. Furthermore, failure to achieve our operational goals may inhibit our targeted growth plans and the successful implementation of our strategic objectives. 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.

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 health care utilization. A continued weakening of the domestic or global economies or a reduction in customer spending or credit availability, including as a result of actual or potential debt default by certain European countries, could result in decreased health care utilization, downward pricing pressures, the reduction or elimination of third-party payor coverage and/or reimbursement levels for our products, longer sales cycles and delayed or decreased purchases of our products. 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, Europe or other key markets persist, spread, or deteriorate, 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 blood screening product sales to Novartis accounted for 34% of our total product sales for the first three months of 2012 and 35% of our total product sales for 2011. 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 also rely on distributors for the distribution of certain of our products in various territories throughout the world. Distribution rights generally revert back to us upon termination of the distribution agreements.

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. We may also be exposed to risks as a result of transitioning a territory from a distributor sales model to a direct sales model, such as difficulties maintaining relationships with specific customers, hiring appropriately trained personnel or ensuring compliance with local product

registration requirements, any of which could result in lower revenues than we previously received from our distributor in that territory.

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 the development of and marketing for 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 deoxyribonucleic acid, or DNA, sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the initial term of the collaboration will end on the earlier of December 15, 2012 or six months after Pacific Biosciences demonstrates the proof of concept of its "V2" single-molecule DNA sequencing system.

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 our agreements with Novartis, Siemens or 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 may also pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. 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 has provided us with access to growth opportunities in transplant diagnostics and genetic testing, and accelerated 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 has supported our strategic focus on commercializing differentiated molecular tests for infectious diseases. In addition, in December 2010 we acquired GTI Diagnostics, which we believe has strengthened our transplant diagnostics business and provided 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;
- 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, may in turn 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 or instruments we may develop, such as our PANTHER instrument system, may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and these and other new products or

instruments 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.

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, Becton, Dickinson and Company, or 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 a 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 NATs 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 may also 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 NATs 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.

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. 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.

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.

Our products are subject to various governmental regulations, which may result in us incurring significant compliance costs or experiencing delays or difficulties in commercializing our products.

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, or IOM, released a related report on the 510(k) regulatory process in July 2011. The FDA is reviewing the IOM's report as well as public input to determine what, if any, recommendations the FDA will adopt with respect to the 510(k) regulatory process. Many of the actions proposed by the CDRH could result in significant changes to the 510(k) regulatory 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 authorizations, pricing and reimbursement vary widely from country to country. Our European Union, or EU, foreign marketing authorizations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

The process of seeking and obtaining regulatory approvals to market our products, particularly from the FDA and some foreign governmental authorities, can be costly and time consuming, and approvals might not be granted for future products on a timely basis, or at all. In addition, unexpected complications in conducting clinical trials could cause us to incur unanticipated expenses or result in delays or difficulties in receiving FDA approval or clearance. In May 2011, we submitted an application to the FDA for clearance to use our PANTHER instrument system to run our APTIMA Combo 2 assay. There can be no assurances as to whether the use of our PANTHER instrument system 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 clearance or approval of our PANTHER instrument system or 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.

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 ribonucleic acid, or RNA, and for use in the detection of Trichomonas vaginalis RNA. We also have developed an ASR for the detection of HCV RNA 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.

In addition to ASRs, certain research use only, or RUO, products may be sold in the United States without 510(k) clearance or premarket approval from the FDA. The FDA generally considers RUO products as products that are in the laboratory research phase of development and which are not represented as an effective in vitro diagnostic product. We currently sell certain RUO products for immunology and DNA extraction purposes. In June 2011, the FDA issued draft guidance indicating that RUO product manufacturers should not sell RUO products to customers whom they know use the product for clinical diagnostic use. Comments to the FDA's draft guidance were due in August 2011. If the FDA issues final guidance imposing obligations on RUO product manufacturers as proposed in the draft guidance, we will be subject to additional restrictions, which may include potentially having to cease sales of RUO products to

certain customers, and we will likely incur increased compliance costs related to the sale of our RUO products.

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 May 2011, we voluntarily recalled certain Elucigene test kits for the detection of genetic mutations associated with cystic fibrosis because of issues we identified during quality control stability testing. All affected customers and appropriate regulatory authorities have been advised of the voluntary recall and we have made a substitute product available. The affected product is CE marked, but is not cleared by the FDA and is not available for sale in the United States. In addition, in May 2011 we initiated a second voluntary recall of certain Elucigene branded tests in Canada upon determination that such products were not properly registered with Health Canada. In April 2012, we voluntarily recalled certain lots of LIFECODES PAK (platelet antibody) products after determining that the negative controls in the assays were increasing signals over time, leading to the potential for decreased product performance. All affected customers have been advised of the voluntary recall and we have made replacement products available. We have classified this event as a Class III recall under the FDA's classification system.

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 further voluntary recalls, and any such recalls could divert managerial and financial resources, could be more difficult and costly to correct, could result in the suspension of sales of certain of our products and could harm our reputation and our financial results.

Our gross profit margin percentage on the sale of blood screening assays may decrease upon the implementation of smaller pool sizes or individual donor testing.

We currently receive revenues from the sale of blood screening assays primarily for use with pooled donor samples, particularly in the United States. 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 primarily on a per donation basis, our profit margins are greater when a single test can be used to screen multiple donor samples.

Many international blood screening markets have transitioned from pooled testing of large numbers of donor samples to smaller pool sizes or individual donor testing, or IDT. A greater number of tests are required in markets which have adopted smaller pool sizes or IDT. Under our 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 or IDT will increase our variable manufacturing costs, including costs of raw materials and labor. If the price per donor or total sales volume does not increase in line with the increase in our total variable manufacturing costs, our gross profit margin percentage from sales of blood screening assays will decrease upon adoption of smaller pool sizes or IDT. 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 or IDT, because we do not know the ultimate selling price that Novartis may charge to the end user or the degree to which smaller pool sizes or IDT 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 pursuant to our collaboration agreement with Novartis. Product sales from our blood screening collaboration with Novartis accounted for 34% of our total product

sales for the first three months of 2012 and 35% of our total product sales for 2011. Our blood screening collaboration with Novartis is largely dependent on two significant customers in the United States, The American Red Cross 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 our total revenues during the first three months of 2012 and 2011. 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 590 U.S. and foreign patents covering our products and technologies as of March 31, 2012, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by February 16, 2030 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.

In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011 the United States enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the United States from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the United States. Any patents issued to us or our collaborators may not provide us with any competitive advantages, and the patents held by other parties may limit our freedom to conduct our business or use our technologies. Our efforts to enforce and maintain our intellectual property rights may not be successful and may result in substantial costs and diversion of management time. Even if our rights are valid, enforceable and broad in scope, third parties may develop competing products based on technology that is not covered by our patents.

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

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

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. From time-to-time in the ordinary course of business, we receive communications from third

parties calling our attention to patents or other intellectual property rights owned by them, with the implicit or explicit suggestion that we may need to acquire a license of such rights. We have faced in the past, and may face in the future, patent infringement lawsuits by companies that control patents for products and services similar to ours or other lawsuits alleging infringement by us of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may choose to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management's attention from other business concerns. The cost of such litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

In October 2009, we filed a patent infringement action against BD in the United States 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 United States 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 the detection of 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 United States District Court for the District of Columbia challenging the decisions of the Patent and Trademark Office in the patent interference cases. From November 2007 through September 2008, the parties engaged in settlement negotiations and then notified the court that they had signed a memorandum of understanding prior to the negotiation of final, definitive settlement documents. In May 2008, we signed a license agreement with Institut Pasteur concerning Institut Pasteur's intellectual property for the molecular detection of HIV, covering products manufactured and sold through, and under, our brands or name. In September 2008, the parties to the pending litigation in the United States District Court for the District of Columbia informed the court that they were unable to reach a final, definitive agreement and intended to proceed with litigation. There can be no assurances as to the ultimate outcome of the interference litigation and no assurances as to how the outcome of the interference litigation may affect the patent rights we licensed from Institut Pasteur, or Novartis' right to sell HIV blood screening tests.

The United States 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. The term of our credit facility with Bank of America has been extended three times and currently expires in February 2013. As of March 31, 2012, the total principal amount outstanding under the revolving credit facility was $248.0 million.

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

- increase our vulnerability to general adverse economic and industry conditions;

- have a material adverse effect on our business and financial condition if we are unable to service our indebtedness or refinance such indebtedness;

- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- place us at a disadvantage compared to our competitors that have less indebtedness; and
- expose us to higher interest expense in the event of increases in interest rates because indebtedness under our credit facility bears interest at a variable rate.

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

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

While there is a federal preemption defense against product liability claims for medical products that receive premarket approval from the FDA, such defense may not be available for products that we market under a 510(k) clearance. As such, we are subject to potential product liability claims as a result of the design, development, manufacture and marketing of certain of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could cause an increase in 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 limited or 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, 2012, we had approximately $515.9 million of long-lived assets, including $18.0 million of capitalized software, net of accumulated amortization, relating primarily to our TIGRIS and PANTHER instruments, goodwill of $140.4 million, a $5.4 million investment in Qualigen, Inc., a $5.0 million investment in DiagnoCure, Inc., or DiagnoCure, a $4.7 million investment in Roka Bioscience, Inc., and $162.1 million of capitalized licenses and manufacturing access fees, patents, purchased intangible assets and other long-term assets. Additionally, we had $67.0 million of land and buildings, $36.8 million of building improvements, $75.3 million of equipment and furniture and fixtures, and $1.2 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 be profitable in the period in which the charge is taken or otherwise fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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

A change in accounting standards or practices, or a change in existing taxation rules or practices, can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or standards, such as the potential requirement that United States 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 R&D spending, the outcome of audits by federal, state and foreign jurisdictions, the availability of the federal R&D tax credit and, in some instances, the timing of when this tax credit is made available to us, 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.

Historically, 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 that our R&D expense levels will remain high 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 R&D expenses as a percentage of revenue will decrease in future periods, we may not be able to generate sufficient revenues to maintain current levels of profitability in the future. A potential reduction of profitability in the future could cause the market price of our common stock to decline.

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

We engage one or more third parties to manage some of our cash consistent with an investment policy that restricts investments to debt securities of high credit quality, with requirements placed on maturities and concentration by security type and issuer. 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. In the third quarter of 2011, we recognized a $39.5 million OTTI loss related to our investment in Pacific Biosciences. We may be exposed to additional losses in the value of our investment in Pacific Biosciences as a result of a further decline in the trading price 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 R&D 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, which we may be unable to develop.

The amplified NAT tests that we produce are significantly more expensive to manufacture than our non-amplified products. As we continue to develop new amplified NAT tests in response to market demands for greater sensitivity, our product costs will increase significantly and our margins may decline. We sell our products in a number of cost-sensitive market categories, and we may not be able to manufacture these more complex amplified tests at costs that would allow us to maintain our historical gross margin percentages. In addition, new products that detect or quantify more than one target organism will contain significantly more complex reagents, which will increase the cost of our manufacturing processes and quality control testing. We or other parties we engage to help us may not be able to manufacture these products at a cost or in quantities that would make these products commercially viable. If we are unable to develop or contract for manufacturing capabilities on acceptable terms for our products under development, we will not be able to conduct pre-clinical, clinical and validation testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates.

Blood screening and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States and the EU, certain products may also require individual lot release testing. Maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other 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 22% of our total revenues for the first three months of 2012 and 28% of our total revenues for 2011. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 66% of our total international revenues for the first three months of 2012 and 51% of our total international revenues for 2011.

We encounter risks inherent in international operations. We expect a significant portion of our sales growth to come from expansion in international markets. In addition, our international sales have increased as a result of our acquisition of Tepnel and other international expansion efforts. If the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. Our international sales also may be limited or disrupted by:

- the imposition of government controls;
- export license requirements;
- economic and political instability;
- price controls;
- trade restrictions and tariffs;
- differing local product preferences and product requirements; and
- changes in foreign medical reimbursement and coverage policies and programs.

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 the rules in the United States 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 chlamydia 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 provided 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. In addition, we have acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure. 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. Similarly, 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 need to obtain additional intellectual property rights in order to commercialize our products. We may be unable to obtain such rights on commercially reasonable terms or at all, which could adversely affect our ability to grow our business.

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

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

Competition for skilled sales, marketing, research, product development, engineering, and technical personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of the services of key personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop new products or enhance existing products in a timely manner, sell products to our customers or manage our business effectively.

If a natural or man-made disaster strikes our manufacturing or warehouse facilities, we may be unable to manufacture or distribute our products for a substantial amount of time and may experience inventory shortfalls, which would cause our sales to decline.

We manufacture substantially all of our products in four manufacturing facilities, two of which are located in San Diego, California, one of which is 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. In addition, we use a third-party logistics provider to store product inventory in the United States. Our facilities, or those of our third-party logistics provider, may be harmed by natural or man-made disasters or events, including, without limitation, earthquakes,

tornadoes, fires and prolonged power outages. In the event any of these facilities is affected by such a disaster or event, we would be forced to rely on third-party manufacturers and may experience inventory shortages. In the event of a disaster or other similar event, 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 R&D and manufacturing activities involve the controlled use of infectious agents and 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. Among other things, the provisions of our amended and restated certificate of incorporation and amended and restated bylaws:

- 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% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisition of additional shares, for a three-year period following the date on which that person or its affiliate crosses the 15% 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 will likely 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 the results of our consolidated operations, our financial position and cash flows in an accurate and timely manner and to otherwise operate our business in a secure environment, all of which could adversely affect our financial results, stock price and reputation.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and Nasdaq Global Select Market rules, are creating uncertainty for companies such as ours. To maintain high standards of corporate governance and public disclosure, we have invested, and intend to continue to invest, in reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

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

The following table summarizes our common stock repurchase activity during the first quarter of 2012:

	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, 2012	—	$—	—	$—
February 1-29, 2012	16,212	69.30	—	—
March 1-31, 2012	—	—	—	—
Total [(1)]	16,212		—	

(1) During the first quarter of 2012, we repurchased and retired a total of 16,212 shares of our common stock, at an average price of $69.30, 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 4. Mine Safety Disclosures

Not applicable.

Item 6. Exhibits

See the Exhibit Index and Exhibits filed or furnished in connection with this Quarterly Report.

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 8, 2012

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

DATE: May 8, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
2.1(1)	Agreement and Plan of Merger, dated as of April 29, 2012, by and among Gen-Probe Incorporated, Hologic, Inc. and Gold Acquisition Corp.
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)*	Form of Employee Stock Option Agreement and Grant Notice for use Under the 2003 Incentive Award Plan of Gen-Probe Incorporated (adopted as of February 8, 2012).
10.2(7)*	Amendment Number 1 to Third Amended and Restated Employment Agreement dated as of February 8, 2012 by and between Gen-Probe Incorporated and Carl W. Hull.
10.3(8)	Amendment No. 6 to Credit Agreement dated as of February 10, 2012 by and between Gen-Probe Incorporated, as Borrower, and Bank of America, N.A., as Lender.
10.4†*	Sixth Amendment to the 2003 Incentive Award Plan of Gen-Probe Incorporated (adopted as of February 8, 2012).
10.5†*	Gen-Probe 2012 Employee Bonus Plan.
10.6†*	Gen-Probe Incorporated 2012 Executive Bonus Plan.
31.1†	Certification, dated May 8, 2012, 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 8, 2012, 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 8, 2012, 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 8, 2012, 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.INS‡	XBRL Instance Document.

101.SCH‡ XBRL Schema Document.

101.CAL‡ XBRL Calculation Linkbase Document.

101.LAB‡ XBRL Label Linkbase Document.

101.PRE‡ XBRL Presentation Linkbase Document.

101.DEF‡ XBRL Definition Linkbase Document.

† Filed herewith.
‡ Furnished herewith.
* Indicates management contract or compensatory plan, contract or arrangement.
(1) Incorporated by reference to Gen-Probe's Current Report on Form 8-K filed with the SEC on May 1, 2012.
(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 10, 2012.
(7) Incorporated by reference to Gen-Probe's Current Report on Form 8-K filed with the SEC on February 14, 2012.
(8) Incorporated by reference to Gen-Probe's Current Report on Form 8-K filed with the SEC on February 15, 2012.