

GEN PROBE INC
Form 10-Q
May 05, 2010

Table of Contents

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

(Mark One)

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2010

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Commission File Number 000-49834
GEN-PROBE INCORPORATED
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(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
Offices)

92121
(Zip Code)

(858) 410-8000

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 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 Accelerated filer Non-accelerated filer Smaller Reporting Company

(Do not check if a smaller reporting company)

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

As of April 30, 2010, there were 49,609,967 shares of the registrant's common stock, par value \$0.0001 per share, outstanding.

**GEN-PROBE INCORPORATED
TABLE OF CONTENTS
FORM 10-Q**

| | Page |
|--|-------------|
| PART I FINANCIAL INFORMATION | |
| Item 1. Consolidated Financial Statements | |
| <u>Consolidated Balance Sheets</u> | 3 |
| <u>Consolidated Statements of Income</u> | 4 |
| <u>Consolidated Statements of Cash Flows</u> | 5 |
| <u>Notes to Consolidated Financial Statements</u> | 6 |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 25 |
| <u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u> | 34 |
| <u>Item 4. Controls and Procedures</u> | 35 |
| PART II OTHER INFORMATION | |
| <u>Item 1. Legal Proceedings</u> | 36 |
| <u>Item 1A. Risk Factors</u> | 36 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 53 |
| <u>Item 6. Exhibits</u> | 54 |
| SIGNATURES | 55 |
| <u>EX-10.106</u> | |
| <u>EX-31.1</u> | |
| <u>EX-31.2</u> | |
| <u>EX-32.1</u> | |
| <u>EX-32.2</u> | |

Table of Contents

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

| | March 31, 2010 (unaudited) | December 31, 2009 |
|--|---|----------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents, including restricted cash of \$16 and \$17 at March 31, 2010 and December 31, 2009, respectively | \$ 187,277 | \$ 82,616 |
| Marketable securities | 273,606 | 402,990 |
| Trade accounts receivable, net of allowance for doubtful accounts of \$443 and \$516 at March 31, 2010 and December 31, 2009, respectively | 46,860 | 55,305 |
| Accounts receivable - other | 5,177 | 4,707 |
| Inventories | 59,826 | 61,071 |
| Deferred income tax | 14,582 | 13,959 |
| Prepaid income tax | | 7,317 |
| Prepaid expenses | 16,910 | 14,747 |
| Other current assets | 4,771 | 4,708 |
| Total current assets | 609,009 | 647,420 |
| Marketable securities, net of current portion | 73,404 | 15,472 |
| Property, plant and equipment, net | 158,140 | 157,437 |
| Capitalized software, net | 12,996 | 12,560 |
| Goodwill | 122,171 | 122,680 |
| Purchased intangibles, net | 105,090 | 108,015 |
| License, manufacturing access fees and other assets, net | 64,036 | 64,601 |
| Total assets | \$ 1,144,846 | \$ 1,128,185 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 18,218 | \$ 26,750 |
| Accrued salaries and employee benefits | 21,748 | 27,093 |
| Other accrued expenses | 22,359 | 18,460 |
| Income tax payable | 2,744 | |
| Short-term borrowings | 240,796 | 240,841 |
| Deferred revenue | 2,833 | 3,527 |
| Total current liabilities | 308,698 | 316,671 |
| Non-current income tax payable | 6,103 | 5,958 |
| Deferred income tax | 22,522 | 23,220 |
| Deferred revenue, net of current portion | 1,723 | 1,978 |
| Other long-term liabilities | 5,077 | 13,183 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |

Edgar Filing: GEN PROBE INC - Form 10-Q

| | | |
|--|--------------|--------------|
| 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, 49,520,437 and 49,143,798 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively | 5 | 5 |
| Additional paid-in capital | 256,026 | 242,615 |
| Accumulated other comprehensive income | 560 | 4,616 |
| Retained earnings | 544,132 | 519,939 |
| Total stockholders' equity | 800,723 | 767,175 |
| Total liabilities and stockholders' equity | \$ 1,144,846 | \$ 1,128,185 |

See accompanying notes to consolidated financial statements.

Table of Contents

GEN-PROBE INCORPORATED
CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

(Unaudited)

| | Three Months Ended | |
|---|---------------------------|---------------|
| | March 31, | |
| | 2010 | 2009 |
| Revenues: | | |
| Product sales | \$ 130,569 | \$ 112,522 |
| Collaborative research revenue | 3,264 | 1,675 |
| Royalty and license revenue | 1,586 | 1,986 |
| Total revenues | 135,419 | 116,183 |
| Operating expenses: | | |
| Cost of product sales (excluding acquisition-related intangible amortization) | 42,661 | 33,314 |
| Acquisition-related intangible amortization | 2,216 | |
| Research and development | 29,681 | 24,998 |
| Marketing and sales | 14,781 | 11,055 |
| General and administrative | 14,679 | 13,846 |
| Total operating expenses | 104,018 | 83,213 |
| Income from operations | 31,401 | 32,970 |
| Other income/(expense): | | |
| Investment and interest income | 3,898 | 4,882 |
| Interest expense | (546) | (151) |
| Gain on contingent consideration | 1,745 | |
| Other expense, net | (159) | (142) |
| Total other income, net | 4,938 | 4,589 |
| Income before income tax | 36,339 | 37,559 |
| Income tax expense | 12,146 | 11,812 |
| Net income | \$ 24,193 | \$ 25,747 |
| Net income per share: | | |
| Basic | \$ 0.49 | \$ 0.49 |
| Diluted | \$ 0.48 | \$ 0.49 |
| Weighted average shares outstanding: | | |
| Basic | 49,233 | 52,157 |
| Diluted | 49,739 | 52,833 |

See accompanying notes to consolidated financial statements.

Table of Contents

GEN-PROBE INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

| | Three Months Ended | |
|---|---------------------------|-------------|
| | March 31, | |
| | 2010 | 2009 |
| Operating activities | | |
| Net income | \$ 24,193 | \$ 25,747 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 11,308 | 8,748 |
| Amortization of premiums on investments, net of accretion of discounts | 2,216 | 1,523 |
| Stock-based compensation charges | 5,902 | 5,758 |
| Stock-based compensation income tax benefits | 1,156 | 126 |
| Excess tax benefit from employee stock-based compensation | (1,596) | (127) |
| Deferred revenue | (833) | 147 |
| Deferred income tax | (1,360) | 1,305 |
| Gain on contingent consideration | (1,745) | |
| Loss on disposal of property and equipment | 47 | |
| Changes in assets and liabilities: | | |
| Trade and other accounts receivable | 7,696 | (784) |
| Inventories | 1,110 | 2,223 |
| Prepaid expenses | (2,200) | 945 |
| Other current assets | (95) | 436 |
| Other long-term assets | (257) | (1,161) |
| Accounts payable | (8,065) | (219) |
| Accrued salaries and employee benefits | (5,256) | (5,657) |
| Other accrued expenses | (1,630) | 2,217 |
| Income tax payable | 10,671 | 10,709 |
| Other long-term liabilities | (575) | 82 |
| Net cash provided by operating activities | 40,687 | 52,018 |
| Investing activities | | |
| Proceeds from sales and maturities of marketable securities | 139,425 | 84,008 |
| Purchases of marketable securities | (71,390) | (37,124) |
| Purchases of property, plant and equipment | (7,828) | (7,525) |
| Additions to capitalized software | (1,089) | |
| Purchases of intangible assets, including license and manufacturing access fees | (722) | (205) |
| Other assets | (310) | (13) |
| Net cash provided by investing activities | 58,086 | 39,141 |
| Financing activities | | |
| Excess tax benefit from stock-based compensation | 1,596 | 127 |
| Repurchase and retirement of restricted stock for payment of taxes | (39) | (34) |
| Repurchase and retirement of common stock | (10,961) | (35,627) |
| Proceeds from issuance of common stock and ESPP | 16,912 | 534 |

Edgar Filing: GEN PROBE INC - Form 10-Q

| | | |
|--|------------|------------|
| Borrowings under credit facility | | 170,000 |
| Net cash provided by financing activities | 7,508 | 135,000 |
| Effect of exchange rate changes on cash and cash equivalents | (1,620) | (86) |
| Net increase in cash and cash equivalents | 104,661 | 226,073 |
| Cash and cash equivalents at the beginning of period | 82,616 | 60,122 |
| Cash and cash equivalents at the end of period | \$ 187,277 | \$ 286,195 |

See accompanying notes to consolidated financial statements.

5

Table of Contents**Notes to the Consolidated Financial Statements (unaudited)****Note 1 Summary of significant accounting policies*****Basis of presentation***

The accompanying interim consolidated financial statements of Gen-Probe Incorporated (Gen-Probe or the Company) at March 31, 2010, and for the three month periods ended March 31, 2010 and 2009, are unaudited and have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP) for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In management s opinion, the unaudited consolidated financial statements include all adjustments, consisting only of normal recurring accruals, necessary to state fairly the financial information therein, in accordance with U.S. GAAP. Interim results are not necessarily indicative of the results that may be reported for any other interim period or for the year ending December 31, 2010.

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

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

Principles of consolidation

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

In April 2009, the Company completed its acquisition of Tepnel Life Sciences plc (Tepnel), a United Kingdom (UK) based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd. Tepnel s transplant diagnostics and genetic testing businesses are included in the Company s clinical diagnostic operations beginning in April 2009. While Tepnel s research products and services business represents a new area of business for the Company, the activities of the research products and services business were immaterial to the Company s overall operations for the three months ended March 31, 2010.

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

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

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts reported in the consolidated financial statements. These estimates include assessing the collectability of accounts receivable, recognition of revenues, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; liabilities associated with employee benefit costs; 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.

Table of Contents***Marketable securities***

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

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

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

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

The Company does not consider its investments in marketable securities with a current unrealized loss position to be other-than-temporarily impaired at March 31, 2010 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. However, investments in an unrealized loss position deemed to be temporary at March 31, 2010 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption "Marketable securities, net of current portion," reflecting the Company's current intent and ability to hold such investments to maturity. The Company has determined that its investments in municipal securities should be classified as available-for-sale.

Revenue recognition

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

The Company manufactures blood screening products according to demand specifications of its collaboration partner, Novartis Vaccines and Diagnostics, Inc. (Novartis). Upon shipment to Novartis, the Company recognizes blood screening product sales at an agreed upon transfer price and records the related cost of products sold. Based on the terms of the Company's collaboration agreement with Novartis, the Company's ultimate share of the net revenue from sales to the end user is not known until reported to the Company by Novartis. The Company then adjusts blood screening product sales upon receipt of customer revenue reports and a net payment from Novartis of amounts reflecting the Company's ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized. The Company amended its collaboration agreement with Novartis effective as of January 1, 2009 to decrease the time period between product sales and net payment of the Company's share of blood screening assay revenue from 45 days to 30 days.

Generally, the Company provides its instrumentation to reference laboratories, public health institutions and hospitals without requiring them to purchase the equipment or enter into an equipment lease. Instead, the Company recovers the cost of providing the instrumentation in the amount it charges for its diagnostic assays. The depreciation costs associated with an instrument are charged to cost of product sales on a straight-line basis over the estimated life of the instrument. The costs to maintain these instruments in the field are charged to cost of product sales as incurred.

The Company sells its instruments to Novartis for use in blood screening and records these instrument sales upon delivery since Novartis is responsible for the placement, maintenance and repair of the units with its customers. The

Company also sells instruments to its clinical diagnostics customers and records sales of these instruments upon delivery and receipt of customer acceptance. Prior to delivery, each instrument is tested to meet

7

Table of Contents

Gen-Probe's and United States Food and Drug Administration (FDA) specifications, and is shipped fully assembled. Customer acceptance of the Company's clinical diagnostic instrument systems requires installation and training by the Company's technical service personnel. Generally, installation is a standard process consisting principally of uncrating, calibrating and testing the instrumentation.

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

The Company records revenue on its research products and services in the period during which the related costs are incurred, or services are provided. These revenues consist of outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

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

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

Royalty revenue is recognized related to the sale or use of the Company's products or technologies under license agreements with third parties. For those arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and adjusts for differences between the estimated and actual royalties in the following period. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenue upon receipt of royalty statements from the applicable licensee.

Stock-based compensation

The Company's unrecognized stock-based compensation expense as of March 31, 2010, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards was approximately as follows (in thousands, except number of years):

| Awards | Weighted Average Remaining Expense Life (Years) | Unrecognized Expense as of |
|---------------|--|---------------------------------------|
|---------------|--|---------------------------------------|

| | | March 31, 2010 |
|------------------------------------|-----|---------------------------|
| Options | 2.8 | \$ 35,101 |
| Employee stock purchase plan | 0.2 | 113 |
| Performance share awards | 1.5 | 2,396 |
| Restricted stock | 2.1 | 6,626 |
| Deferred issuance restricted stock | 2.5 | 1,817 |
| | | \$ 46,053 |

Table of Contents

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, 2010 and 2009 (in thousands):

| | Three Months Ended March 31, | |
|----------------------------|---|-----------------|
| | 2010 | 2009 |
| Cost of product sales | \$ 864 | \$ 798 |
| Research and development | 1,679 | 1,702 |
| Marketing and sales | 802 | 759 |
| General and administrative | 2,557 | 2,499 |
| Total | \$ 5,902 | \$ 5,758 |

The Company used the following weighted average assumptions to estimate the fair value of options granted under the Company's equity incentive plans and the shares purchasable under the Company's Employee Stock Purchase Plan (ESPP) for the three month periods ended March 31, 2010 and 2009:

| | Stock Option Plans | | ESPP | |
|------------------------------|---------------------------|-------------|-------------|-------------|
| | 2010 | 2009 | 2010 | 2009 |
| Risk-free interest rate | 2.1% | 1.6% | 0.2% | 1.3% |
| Volatility | 32% | 37% | 26% | 47% |
| Dividend yield | | | | |
| Expected term (years) | 4.4 | 4.2 | 0.5 | 0.5 |
| Resulting average fair value | \$12.66 | \$12.96 | \$9.65 | \$12.20 |

Net income per share

Basic earnings per share is computed using the two-class method. Under the two-class method, net income is allocated to common stock and participating securities. Basic net income per share is computed by dividing net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing net income for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share when the combined exercise price, average unamortized fair values and assumed tax benefits upon exercise are greater than the average market price for the Company's common stock because their effect is anti-dilutive. Potentially dilutive securities totaling approximately 4,179,000 and 3,595,000 shares for the three month periods ended March 2010 and 2009, respectively, were excluded from the calculation of diluted earnings per share below because of their anti-dilutive effect.

Table of Contents

The following table sets forth the computation of net income per share for the three month periods ended March 31, 2010 and 2009 (in thousands, except per share amounts):

| | Three Months Ended March 31, | | | | | |
|---|------------------------------|-----------------------|------------------------|-----------------------------|-----------------------|------------------------|
| | 2010 Weighted Average | | | 2009 Weighted Average | | |
| | Income | Shares Outstanding | Per Share Amount | Income | Shares Outstanding | Per Share Amount |
| Net income | \$ 24,193 | | | \$ 25,747 | | |
| Less: Earnings allocated to unvested shareholders | (101) | | | (103) | | |
| Basic EPS | | | | | | |
| Distributable income available to common shareholders | 24,092 | 49,233 | \$ 0.49 | 25,644 | 52,157 | \$ 0.49 |
| Effect of dilutive securities: | | | | | | |
| Add back: Undistributed earnings allocated to unvested shareholders | 101 | | | 103 | | |
| Dilutive stock options | | 506 | | | 676 | |
| Less: Undistributed earnings reallocated to unvested shareholders | (100) | | | (102) | | |
| Diluted EPS - Common shares | \$ 24,093 | 49,739 | \$ 0.48 | \$ 25,645 | 52,833 | \$ 0.49 |

Pending adoption of recent accounting pronouncements*Accounting Standards Update 2010-3*

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

Accounting Standards Update 2009-13

In September 2009, the FASB revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for the Company's fiscal year beginning January 1, 2011

with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company is currently evaluating early prospective adoption and determining the effects, if any, the adoption of this guidance will have on its consolidated financial statements.

Note 2 Business combinations

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

Acquisition of Tepnel Life Sciences plc

In April 2009, the Company acquired Tepnel, a UK-based international life sciences products and services company, now known as Gen-Probe Life Sciences Ltd., which has two principal businesses, molecular diagnostics

Table of Contents

and research products and services. As a result of the acquisition, Tepnel became a wholly-owned subsidiary of the Company.

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

The allocation of the purchase price for the acquisition of Tepnel, which was finalized during the first quarter of 2010, is as follows (in thousands):

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

- (1) Difference caused by exchange rate fluctuations between the date of acquisition and the date funds were wired.

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

| | |
|--------------------------|-----------|
| Patents | \$ 294 |
| Software | 441 |
| Customer relationships | 45,439 |
| Trademarks / trade names | 11,323 |
| Total | \$ 57,497 |

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

retention rate of the acquired businesses and the historical and projected growth of revenues and related cash flows. The Company will monitor and assess the acquired intangible assets and will adjust, if necessary, the expected life, amortization method or carrying value of such assets to best match the underlying economic value.

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

Table of Contents

value of the after-tax free cash flows attributable to owning the intangible asset. The discount rates used in these valuation methods range from 12 to 13 percent.

The estimated amortization expense for these assets over future periods is as follows (in thousands):

| Years ending December 31, | |
|----------------------------------|------------------|
| Remainder of 2010 | \$ 3,102 |
| 2011 | 4,136 |
| 2012 | 4,136 |
| 2013 | 4,136 |
| 2014 | 4,069 |
| Thereafter | 29,546 |
| Total | \$ 49,125 |

Acquisition of Prodesse, Inc.

In October 2009, the Company acquired Prodesse, a privately held Wisconsin corporation, for approximately \$60.0 million, subject to a designated pre-closing operating income adjustment. The Company may also be required to make additional cash payments to former Prodesse securityholders of up to an aggregate of \$25.0 million based on the achievement of certain specified performance measures. As a result of the acquisition, Prodesse (which is now known as Gen-Probe Prodesse, Inc.) became a wholly owned subsidiary of the Company. The Company financed the acquisition through existing cash on hand.

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

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

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

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

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

The fair value assigned to trademarks and trade names and developed technology has been determined primarily by using the income approach and a variation of the income approach known as the relief from royalty method,

Table of Contents

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

In addition to acquiring the existing Prodesse products, the Company also acquired other products that can be classified as next generation products, which are in the process of being developed. Overall, an insignificant value of approximately \$1.1 million was classified as in-process research and development for the products under development. The Company estimates that it will take approximately \$2.0 million to complete the development of these products and, if successful in the development and approval of these products, the Company anticipates revenues will be generated from these products starting in late 2010.

The estimated amortization expense for these assets over future periods is as follows (in thousands):

| Years Ending December 31, | |
|----------------------------------|------------------|
| Remainder of 2010 | \$ 3,564 |
| 2011 | 4,752 |
| 2012 | 4,752 |
| 2013 | 4,752 |
| 2014 | 4,752 |
| Thereafter | 32,948 |
| Total | \$ 55,520 |

Changes in goodwill resulting from acquisitions

The \$137.1 million purchase price for Tepnel exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company allocated \$70.4 million to goodwill. Included in this initial goodwill amount was \$14.1 million related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired intangible assets. During the first quarter of 2010, the Company made a \$0.4 million adjustment to the goodwill recognized as part of its acquisition of Tepnel based on additional information received during the period. This adjustment resulted in an increase in the estimated value of an acquired liability, which is reflected in the Company's consolidated balance sheets under the caption Other accrued expenses. The measurement period for the purchase price allocation related to the Company's acquisition of Tepnel is now closed.

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

Changes in goodwill for the three months ended March 31, 2010 were as follows (in thousands):

| | |
|--|-------------------|
| Goodwill balance as of December 31, 2009 | \$ 122,680 |
| Changes due to foreign translation | (509) |
| Goodwill balance as of March 31, 2010 | \$ 122,171 |

Note 3 Spin-off of industrial testing assets to Roka Bioscience, Inc.

In September 2009, the Company spun-off its industrial testing assets, including the Closed Unit Dose Assay (CUDA) system, to Roka Bioscience, Inc. (Roka), a newly formed private company focused on developing rapid,

highly accurate molecular assays for biopharmaceutical production, water and food safety testing, and other applications. In consideration for the contribution of assets, the Company received shares of preferred stock representing 19.9% of Roka's capital stock on a fully diluted basis.

Table of Contents

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

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

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

Note 4 Fair value measurements

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

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

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

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

Table of Contents**Assets and liabilities measured at fair value on a recurring basis**

The Company's marketable securities include tax advantaged municipal securities, Federal Deposit Insurance Corporation (FDIC) insured corporate bonds and money market funds. When available, the Company generally uses quoted market prices to determine fair value, and classifies such items as Level 1. If quoted market prices are not available, prices are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals. The Company classifies such items as Level 2.

There have been no transfers of assets or liabilities between the fair value measurement classifications during the three months ended March 31, 2010.

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

| | Fair Value Measurements at March 31, 2010 | | | |
|--|---|--|--|--|
| | Quoted prices in active markets for identical assets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) | Total carrying value in the consolidated balance sheets |
| Assets: | | | | |
| Cash equivalents | \$ | \$ 129,694 | \$ | \$ 129,694 |
| Marketable securities | | | | |
| Certificates of deposit | | 1,968 | | 1,968 |
| Treasury securities | | 4,814 | | 4,814 |
| Municipal securities | | 314,400 | | 314,400 |
| Corporate obligations | | 25,828 | | 25,828 |
| Total marketable securities | | 347,010 | | 347,010 |
| Deferred compensation plan assets | | 5,828 | | 5,828 |
| Total assets at fair value | | 482,532 | | 482,532 |
| Liabilities: | | | | |
| Contingent consideration | | | 16,249 | 16,249 |
| Deferred compensation plan liabilities | | 5,415 | | 5,415 |
| Total liabilities at fair value | \$ | \$ 5,415 | \$ 16,249 | \$ 21,664 |

| | Fair Value Measurements at December 31, 2009 | | |
|--|---|---------------------------------|------------------------------------|
| | Quoted prices in | Significant unobservable | Total carrying value in the |

| | active markets for identical assets (Level 1) | Significant other observable inputs (Level 2) | inputs (Level 3) | consolidated balance sheets |
|--|--|--|-----------------------------|--|
| Assets: | | | | |
| Cash equivalents | \$ | \$ 13,000 | \$ | \$ 13,000 |
| Marketable securities | | | | |
| Certificates of deposit | | 1,961 | | 1,961 |
| Municipal securities | | 324,252 | | 324,252 |
| Corporate obligations | | 92,249 | | 92,249 |
| Total marketable securities | | 418,462 | | 418,462 |
| Deferred compensation plan assets | | 5,671 | | 5,671 |
| Total assets at fair value | | 437,133 | | 437,133 |
| Liabilities: | | | | |
| Contingent consideration | | | 17,994 | 17,994 |
| Deferred compensation plan liabilities | | 5,700 | | 5,700 |
| Total liabilities at fair value | \$ | \$ 5,700 | \$ 17,994 | \$ 23,694 |

Table of Contents

For those financial instruments with significant Level 3 inputs, the following table summarizes the activity for the three months ended March 31, 2010 (in thousands):

| | |
|--|-----------|
| Level 3 contingent consideration as of December 31, 2009 | \$ 17,994 |
| Gain included in other income/(expense) | (1,745) |
| Level 3 contingent consideration as of March 31, 2010 | \$ 16,249 |

The range of potential contingent consideration that the Company may pay related to the acquisition of Prodesse is between \$0 and \$25.0 million. This range is tied to multiple performance measures including commercial and regulatory milestones. To the extent these milestones are earned, payments of up to \$25.0 million in total will be made, most likely between the third quarter of 2010 and the first quarter of 2012. The Company initially recorded \$18.0 million as the fair value of this potential contingent consideration liability as of December 31, 2009. To assess the fair value of this contingent consideration the Company performed a calculation as of March 31, 2010 that contemplated the current forecasted achievement of the underlying milestones as well as the timing of the related cash payments. These amounts were discounted based on the discount rate established for the Prodesse acquisition as determined in the valuation and purchase price allocation work completed in the fourth quarter of 2009. As a result of this calculation the fair value of this contingent consideration as of March 31, 2010 was reduced to \$16.2 million.

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

Certain assets and liabilities, including cost method investments, are measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances, for example, when there is evidence of impairment. The Company's assets which are evaluated on a non-recurring basis include investments in public and private companies, which are described below.

Equity investment in public company

In April 2009, the Company made a \$5.0 million preferred stock investment in DiagnoCure, Inc. (DiagnoCure), a publicly held company traded on the Toronto Stock Exchange. The Company's equity investment was initially valued based on the transaction price under the cost method of accounting. The market value of the underlying common stock is the most observable value of the preferred stock, but because there is no active market for these preferred shares the Company has classified its equity investment in DiagnoCure as Level 2 in the fair value hierarchy. The Company's investment in DiagnoCure, which totaled \$5.0 million as of March 31, 2010, is included in Licenses, manufacturing access fees and other assets, net on the Company's consolidated balance sheets.

Equity investments in private companies

The valuation of investments in non-public companies requires significant management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such assets. The Company's equity investments in private companies are initially valued based upon the transaction price under the cost method of accounting. Equity investments in non-public companies are classified as Level 3 in the fair value hierarchy.

In September 2009, the Company spun-off its industrial testing assets to Roka, a newly formed private company. In consideration for the contribution of assets, the Company received shares of preferred stock representing 19.9% of Roka's capital stock on a fully diluted basis. The Company's investment in Roka totaled approximately \$0.7 million as of March 31, 2010, and is included in Licenses, manufacturing access fees and other assets, net on the Company's consolidated balance sheets.

In 2006, the Company invested in Qualigen, Inc. (Qualigen), a private company. The Company's investment in Qualigen, which totaled approximately \$5.4 million as of March 31, 2010, is also included in Licenses, manufacturing access fees and other assets, net on the Company's consolidated balance sheets.

The Company records impairment charges when an investment has experienced a decline that is deemed to be other-than-temporary. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. Future adverse changes in market conditions or poor operating results of investees could result in losses or an inability to recover the carrying value of the investments, thereby possibly requiring impairment charges

Table of Contents

in the future. When assessing investments in private companies for an other-than-temporary decline in value, the Company considers many factors, including, but not limited to, the following: the share price from the investee's latest financing round; the performance of the investee in relation to its own operating targets and its business plan; the investee's revenue and cost trends; the investee's liquidity and cash position, including its cash burn rate; and market acceptance of the investee's products and services. From time to time, the Company may consider third party evaluations or valuation reports. The Company also considers new products and/or services that the investee may have forthcoming, any significant news specific to the investee, the investee's competitors and/or industry and the outlook of the overall industry in which the investee operates. In the event the Company's judgments change as to other-than temporary declines in value, the Company may record an impairment loss, which could have an adverse effect on its results of operations.

Note 5 Balance sheet information

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

Inventories

| | March 31, 2010 | December 31, 2009 |
|----------------------------|-------------------------------|----------------------------------|
| Raw materials and supplies | \$ 13,861 | \$ 13,260 |
| Work in process | 22,999 | 23,656 |
| Finished goods | 22,966 | 24,155 |
| | \$ 59,826 | \$ 61,071 |

Property, plant and equipment, net

| | March 31, 2010 | December 31, 2009 |
|--|---------------------------|----------------------------------|
| Land | \$ 19,268 | \$ 19,268 |
| Building | 80,108 | 80,130 |
| Machinery and equipment | 181,124 | 175,885 |
| Building improvements | 43,653 | 42,718 |
| Furniture and fixtures | 17,754 | 17,705 |
| Construction in-progress | 367 | 457 |
| Property, plant and equipment, at cost | 342,274 | 336,163 |
| Less accumulated depreciation and amortization | (184,134) | (178,726) |
| Property, plant and equipment, net | \$ 158,140 | \$ 157,437 |

Purchased intangibles, net

| | March 31, 2010 | December 31, 2009 |
|--------------------------------|---------------------------|----------------------------------|
| Purchased intangibles, at cost | \$ 144,724 | \$ 145,502 |
| Less accumulated amortization | (39,634) | (37,487) |

| | | |
|----------------------------|------------|------------|
| Purchased intangibles, net | \$ 105,090 | \$ 108,015 |
|----------------------------|------------|------------|

Table of Contents***License, manufacturing access fees and other assets, net***

| | March 31, 2010 | December 31, 2009 |
|--|---------------------------|----------------------------------|
| Patents | \$ 19,145 | \$ 19,042 |
| License and manufacturing access fees | 62,604 | 62,502 |
| Investment in Qualigen | 5,404 | 5,404 |
| Investment in DiagnoCure | 5,000 | 5,000 |
| Investment in Roka | 725 | 725 |
| Other assets | 7,995 | 7,740 |
| License, manufacturing access fees and other assets, at cost | 100,873 | 100,413 |
| Less accumulated amortization | (36,837) | (35,812) |
| License, manufacturing access fees and other assets, net | \$ 64,036 | \$ 64,601 |

Other accrued expenses

| | March 31, 2010 | December 31, 2009 |
|--------------------------|-------------------------------|----------------------------------|
| Contingent consideration | \$ 14,172 | \$ 8,396 |
| Royalties | 2,935 | 2,907 |
| Professional fees | 1,451 | 1,175 |
| Interest | 736 | 726 |
| Contingent liability | 410 | 433 |
| Warranty | 300 | 334 |
| Other | 2,355 | 4,489 |
| Other accrued expenses | \$ 22,359 | \$ 18,460 |

Note 6 Marketable securities

The Company's marketable securities include tax advantaged municipal securities and FDIC insured corporate bonds with a minimum Moody's credit rating of A3 or a Standard & Poor's credit rating of A-. As of March 31, 2010, the Company did not hold auction rate securities and has never held any such securities. The Company's investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At March 31, 2010, the Company's portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody's.

The following is a summary of the Company's marketable securities as of March 31, 2010 (in thousands):

| Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---------------------------|---------------------------------------|--|---------------------------------|
| \$ 345,632 | \$ 1,776 | \$ (398) | \$ 347,010 |

The following table shows the estimated fair values and gross unrealized losses for the Company's investments in individual securities that have been in a continuous unrealized loss position deemed to be temporary for less than

Edgar Filing: GEN PROBE INC - Form 10-Q

12 months and for more than 12 months as of March 31, 2010 (in thousands):

| Less than 12 Months | | More than 12 Months | |
|----------------------------|-------------------|----------------------------|-------------------|
| Estimated | Unrealized | Estimated | Unrealized |
| Fair | | Fair | |
| Value | Losses | Value | Losses |
| \$ 73,656 | \$ (396) | \$ 2,604 | \$ (2) |

Table of Contents

The unrealized losses on certain of the Company's investments in municipal securities were caused by interest rate increases. At March 31, 2010 and December 31, 2009, the Company had 43 securities and 23 securities, respectively, in an unrealized loss position. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost of the investments. The Company does not consider its investments in municipal securities with a current unrealized loss position to be other-than-temporarily impaired at March 31, 2010 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. However, investments in an unrealized loss position deemed to be temporary at March 31, 2010 that have a contractual maturity of greater than 12 months have been classified as non-current marketable securities under the caption Marketable securities, net of current portion, reflecting the Company's current intent and ability to hold such investments to maturity. The Company's investments in municipal securities are classified as available-for-sale.

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

| | March 31, 2010 | December 31, 2009 |
|-----------------------------|---------------------------|----------------------------------|
| Current | \$ 273,606 | \$ 402,990 |
| Non-current | 73,404 | 15,472 |
| Total marketable securities | \$ 347,010 | \$ 418,462 |

The following table shows the gross realized gains and losses from the sale of marketable securities, based on the specific identification method, for the three month periods ended March 31, 2010 and 2009 (in thousands):

| | Three Months Ended March 31, | |
|---|---|-------------|
| | 2010 | 2009 |
| Proceeds from sale of marketable securities | \$ 118,966 | \$ 73,659 |
| Gross realized gains | 2,227 | 1,872 |
| Gross realized losses | | (427) |
| Net realized gains | \$ 2,227 | \$ 1,445 |

Note 7 Short-term borrowings

In February 2009, the Company entered into a credit agreement with Bank of America, which provided for a one-year senior secured revolving credit facility in an amount of up to \$180.0 million that is subject to a borrowing base formula. The revolving credit facility has a sub-limit for the issuance of letters of credit in a face amount of up to \$10.0 million. Advances under the revolving credit facility are intended to be used to consummate the Company's acquisition of Tepnel and for other general corporate purposes. At the Company's option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America's prime rate and (iii) the London Interbank Offered Rate (LIBOR) plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by the Company. In connection with the credit agreement, the Company also entered into a security agreement, pursuant to which the Company secured its obligations under the credit agreement with a first priority security interest in the securities, cash and other investment property held in specified accounts maintained by Merrill Lynch, Pierce, Fenner & Smith Incorporated, an affiliate of Bank of America. In connection with the

execution of the credit agreement with Bank of America, the Company terminated the commitments under its unsecured bank line of credit with Wells Fargo Bank, N.A., effective as of February 27, 2009. There were no amounts outstanding under the Wells Fargo Bank line of credit as of the termination date.

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

Table of Contents

In February 2010, the Company entered into a second amendment to its credit agreement with Bank of America, pursuant to which, among other things, the maturity date of the Company's senior secured revolving credit facility was extended for an additional one-year period. As extended, the credit facility now expires on February 25, 2011. As of March 31, 2010, the total principal amount outstanding under the revolving credit facility was \$240.0 million and the interest rate payable on such outstanding amount was approximately 0.8%.

As a result of the Tepnel acquisition, the Company assumed Tepnel's pre-existing fixed rate term loan, which accrues interest at an effective rate of 6.6%. As of March 31, 2010, the outstanding principal amount under this loan was £0.5 million, or \$0.8 million based on the exchange rate of £1 to \$1.51 as of the balance sheet date.

Note 8 Income tax

As of March 31, 2010, the Company had total gross unrecognized tax benefits of \$7.7 million. The amount of unrecognized tax benefits (net of the federal benefit for state taxes) that would favorably affect the Company's effective income tax rate, if recognized, was \$6.1 million. Material filings subject to future examination are the Company's California returns filed for the 2005 through 2008 tax years, and the U.S. federal returns filed for the 2006 through 2008 tax years.

Note 9 Contingencies***Contingent Consideration***

In connection with the Company's acquisition of Prodesse, the Company may be obligated to make certain payments to former Prodesse securityholders of up to \$25.0 million. The aggregate fair value of these payments was \$16.2 million as of March 31, 2010, and is reflected in the Company's consolidated balance sheets under the captions

Other accrued expenses and Other long-term liabilities.

Litigation

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

Digene Corporation

In December 2006, Digene Corporation (Digene) filed a demand for binding arbitration against F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. (collectively, Roche), with the International Centre for Dispute Resolution (ICDR) of the American Arbitration Association in New York. In July 2007, the ICDR arbitrators granted the Company's petition to join the arbitration. Digene's arbitration demand challenged the validity of the February 2005 supply and purchase agreement between the Company and Roche. Under the supply and purchase agreement, Roche manufactures and supplies the Company with human papillomavirus (HPV) oligonucleotide products. Digene's demand asserted, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting the Company an improper sublicense and sought a determination that the supply and purchase agreement is null and void.

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

In August 2009, the arbitrators issued their final arbitration award, which confirmed the interim award and also granted the Company's motion to recover attorneys' fees and costs from Digene in the amount of approximately \$2.9 million. The Company filed a petition to confirm the arbitration award in the U.S. District Court for the Southern District of New York and Digene filed a petition to vacate or modify the award. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued. The Company will record the \$2.9 million as an offset to general and administrative expense upon cash receipt.

Table of Contents*Becton, Dickinson and Company*

In October 2009, the Company filed a complaint for patent infringement against Becton, Dickinson and Company (BD) in the U.S. District Court for the Southern District of California. The complaint alleges that BD's Viper XTR™ testing system infringes five of the Company's U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint also alleges that BD's ProbeTec™ Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA assays used with the Viper XTR testing system infringe two of the Company's U.S. patents covering penetrable caps for specimen collection tubes. Finally, the complaint alleges that BD has infringed the Company's U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified. The complaint seeks monetary damages and injunctive relief. There can be no assurances as to the final outcome of the litigation.

In March 2010, the Company filed a second complaint for patent infringement against BD in the U.S. District Court for the Southern District of California. The complaint alleges that BD's BD MAX System™ (formerly known as the HandyLab Jaguar system) infringes four of the Company's U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint seeks monetary damages and injunctive relief. There can be no assurances as to the final outcome of the litigation.

Note 10 Stockholders' equity

Changes in stockholders' equity for the three months ended March 31, 2010 were as follows (in thousands):

| | |
|--|------------|
| Balance at December 31, 2009 | \$ 767,175 |
| Net income | 24,193 |
| Other comprehensive income, net | (4,055) |
| Proceeds from the issuance of common stock | 16,912 |
| Purchases of common stock by board members | 42 |
| Repurchase and retirement of common stock | (10,961) |
| Repurchase and retirement of restricted stock for payment of taxes | (39) |
| Stock-based compensation | 5,860 |
| Stock-based compensation income tax benefits | 1,596 |
| Balance at March 31, 2010 | \$ 800,723 |

Comprehensive income

All components of comprehensive income, including net income, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, which includes certain changes in stockholders' equity, such as foreign currency translation of the Company's wholly owned subsidiaries' financial statements and unrealized gains and losses on their available-for-sale securities, are reported, net of their related tax effect, to arrive at comprehensive income.

Table of Contents

Components of comprehensive income, net of income tax, for the three month periods ended March 31, 2010 and 2009 were as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|-------------|
| | 2010 | 2009 |
| Net income, as reported | \$ 24,193 | \$ 25,747 |
| Other comprehensive (loss) income: | | |
| Foreign currency translation adjustment | (2,854) | (60) |
| Change in net unrealized gain (loss) on available-for-sale securities during the period | (2,649) | 3,363 |
| Reclassification adjustments: | | |
| Net realized gain (loss) on available-for-sale securities | 1,448 | (939) |
| Total other comprehensive (loss) income, net | (4,055) | 2,364 |
| Comprehensive income | \$ 20,138 | \$ 28,111 |

Stock Options

A summary of the Company's stock option activity for all equity incentive plans for the three months ended March 31, 2010 is as follows (in thousands, except price per share data and number of years):

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value |
|----------------------------------|---------------------------------|--|--|--|
| Outstanding at December 31, 2009 | 5,890 | \$ 44.96 | | |
| Granted | 920 | 42.75 | | |
| Exercised | (546) | 31.00 | | |
| Cancelled | (69) | 47.85 | | |
| Outstanding at March 31, 2010 | 6,195 | \$ 45.82 | 4.8 | \$ 43,636 |
| Exercisable at March 31, 2010 | 3,718 | \$ 44.76 | 4.0 | \$ 29,612 |

Restricted Stock and Deferred Issuance Restricted Stock

A summary of the Company's restricted stock and deferred issuance restricted stock award activity during the three months ended March 31, 2010 is as follows (in thousands, except price per share data):

| Number of Shares | Weighted Average Grant- Date Fair Value |
|---------------------------------|--|
|---------------------------------|--|

Edgar Filing: GEN PROBE INC - Form 10-Q

| | | | |
|----------------------------------|-----|----|-------|
| Outstanding at December 31, 2009 | 247 | \$ | 51.76 |
| Granted | 1 | | 43.08 |
| Vested and exercised | (3) | | 46.24 |
| Forfeited | (6) | | 50.83 |
| Outstanding at March 31, 2010 | 239 | \$ | 51.83 |

Performance Share Awards

In February 2010, the Company transitioned from its historical practice of granting certain senior Company employees restricted stock awards with time-based vesting provisions only, to granting these employees the right to

Table of Contents

receive a designated number of shares of common stock (the Performance Shares) based on the achievement of specific performance levels related to the Company's 2010 revenues, earnings per share and return on invested capital (collectively, the Performance Share Criteria). The Performance Share awards were granted under the Company's 2003 Incentive Award Plan and are intended to qualify as performance-based compensation under Section 162(m) of the Internal Revenue Code, as amended.

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

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

A summary of the Company's Performance Share award activity for the three months ended March 31, 2010 is as follows (in thousands, except price per share data):

| | Number of Shares | Maximum Shares Eligible to Receive | Weighted Average Grant-Date Fair Value \$ |
|----------------------------------|------------------------|--|---|
| Outstanding at December 31, 2009 | | | |
| Awarded | 70 | 104 | 42.66 |
| Forfeited | (1) | (2) | 42.66 |
| Outstanding at March 31, 2010 | 69 | 102 | \$ 42.66 |

Stock Repurchase Programs

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

In February 2010, the Company's Board of Directors authorized the repurchase of up to \$100.0 million of the Company's common stock over the one year period following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. As of March 31, 2010, the Company repurchased 233,200 shares under this program at an average price of \$47.00, or approximately \$11.0 million in total.

Note 11 Derivative financial instruments

In 2009, the Company began entering into foreign currency forward contracts to reduce its exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies. These forward contracts generally have a maturity of approximately 30 days and were not designated as hedges. Accordingly, these instruments were marked to market at each balance sheet date with changes in fair value recognized in earnings under the caption Other expense, net. The Company did not enter into any foreign currency forward contracts during the three months ended March 31, 2010.

Table of Contents

The following table reflects the effect of these derivative instruments on the consolidated statements of income for the three month periods ended March 31, 2010 and 2009 (in thousands):

| | Location of gain/(loss) recognized in income | Three Months Ended | |
|---|---|-------------------------------|-------------|
| | | March 31, | |
| Derivatives not designated as hedging instruments: | Other expense, net | 2010 | 2009 |
| Foreign currency forward contracts | | \$ | \$ 9 |

Table of Contents**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

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

The following information should be read in conjunction with our March 31, 2010 consolidated interim financial statements and related notes included elsewhere in this quarterly report and with our consolidated financial statements and related notes for the year ended December 31, 2009 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2009. We also urge you to review and consider our disclosures describing various risks that may affect our business, which are set forth under the heading Risk Factors in this quarterly report and in our Annual Report on Form 10-K for the year ended December 31, 2009.

Overview

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

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

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

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

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

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

human papillomavirus, or HPV, which causes cervical cancer;

gene-based markers for prostate cancer;

Trichomonas, a common parasitic STD;

different types of influenza virus and other respiratory infections; and

Table of Contents

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

Recent Events***Financial Results***

Product sales for the first quarter of 2010 were \$130.6 million, compared to \$112.5 million in the same period of the prior year, an increase of 16%. Total revenues for the first quarter of 2010 were \$135.4 million, compared to \$116.2 million in the same period of the prior year, an increase of 17%. Net income for the first quarter of 2010 was \$24.2 million (\$0.48 per diluted share), compared to \$25.7 million (\$0.49 per diluted share) in the same period of the prior year, a decrease of 6%. Our total revenues, net income and fully diluted earnings per share during the first quarter of 2009 included \$8.2 million of additional one-time revenue associated with the renegotiation of our collaboration agreement with Novartis. Our total revenues, net income and fully diluted earnings per share during the first quarter of 2010 included the results of operations of Tepnel and Prodesse, which were not included in our results of operations for the first quarter of 2009.

Stock Repurchase Program

In February 2010, our Board of Directors authorized the repurchase of up to \$100.0 million of our common stock over the one year period following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. As of March 31, 2010, we repurchased 233,200 shares under this program at an average price of \$47.00, or approximately \$11.0 million in total.

Credit Agreement

In February 2010, we amended our credit agreement with Bank of America, N.A., or Bank of America, to extend the maturity date of our senior secured revolving credit facility for an additional one-year period. As extended, the credit facility now expires in February 2011. As of March 31, 2010, the total principal amount outstanding under the revolving credit facility was \$240.0 million and the interest rate payable on such outstanding amount was approximately 0.8%.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our unaudited interim consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these interim consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectability of accounts receivable, and the valuation of the following: stock-based compensation; marketable securities; equity investments in publicly and privately held companies; income tax; liabilities associated with employee benefit costs; inventories; and goodwill and long-lived assets, including patent costs, capitalized software, purchased intangibles and licenses and manufacturing access fees. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates.

We believe there have been no significant changes during the first quarter of 2010 to the items that we disclosed as our critical accounting policies and estimates in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the year ended December 31, 2009.

Pending Adoption of Recent Accounting Pronouncements***Accounting Standards Update 2010-3***

In March 2010, the Financial Accounting Standards Board, or FASB, ratified the final consensus that offers an alternative method of revenue recognition for milestone payments. The guidance states that an entity can make an

Table of Contents

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

Accounting Standards Update 2009-13

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

Results of Operations*(Dollars in millions)*

| | Three Months Ended March 31, | | | |
|--------------------------------|-------------------------------------|-----------------|----------------|---------------|
| | | | \$ | % |
| | 2010 | 2009 | Change | Change |
| Clinical diagnostics | \$ 76.9 | \$ 59.6 | \$ 17.3 | 29% |
| Blood screening | 49.6 | 52.9 | (3.3) | (6)% |
| Research products and services | 4.1 | | 4.1 | N/M |
| Total Product Sales | \$ 130.6 | \$ 112.5 | \$ 18.1 | 16% |
| As a percent of total revenues | 96% | 97% | | |

Our primary source of revenue comes from product sales, which consist primarily of the sale of clinical diagnostics and blood screening products. Our clinical diagnostic product sales consist primarily of the sale of our women's health, virology, other infectious disease, transplant diagnostics, and prostate oncology products. The principal customers for our clinical diagnostics products include reference laboratories, public health institutions and hospitals. The blood screening assays and instruments we manufacture are marketed and distributed worldwide through our collaboration with Novartis under the Procleix and Ultrio trademarks.

We recognize product sales from the manufacture and shipment of tests for screening donated blood at the contractual transfer prices specified in our collaboration agreement with Novartis for sales to end-user blood bank facilities located in countries where our products have obtained governmental approvals. Blood screening product sales are then adjusted monthly corresponding to Novartis' payment to us of amounts reflecting our ultimate share of net revenue from sales by Novartis to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Novartis to third parties, less freight, duty and certain other adjustments specified in our collaboration agreement with Novartis multiplied by our share of the net revenue.

Product sales increased 16% during the first quarter of 2010 compared to the same period of the prior year. This increase was primarily attributed to higher APTIMA assay sales, as well as additional product sales resulting from our acquisitions of Tepnel and Prodesse, partially offset by a decrease in blood screening sales.

Clinical diagnostic product sales

Clinical diagnostic product sales, including assay, instrument and ancillary sales, represented \$76.9 million, or 59% of product sales during the first quarter of 2010, compared to \$59.6 million, or 53% of product sales during the first quarter of 2009. The \$17.3 million increase in clinical diagnostic product sales is primarily attributed to volume gains in our APTIMA product line, as well as the addition of transplant diagnostics, genetic testing and infectious

disease product sales resulting from our acquisitions of Tepnel and Prodesse.

Clinical diagnostics sales also benefited from customer conversion from our non-amplified PACE test to our amplified APTIMA test. In general, the price of our amplified APTIMA test is twice that of our non-amplified

Table of Contents

PACE product. Thus, the conversion from PACE to APTIMA drives an overall increase in product sales even if underlying testing volumes remain the same.

Clinical diagnostic product sales were positively affected during the first quarter of 2010 as compared to the first quarter of 2009 by favorable estimated exchange rate impacts of \$0.9 million due to a weaker U.S. dollar.

Blood screening product sales

Blood screening product sales, including assay, instrument and ancillary sales, represented \$49.6 million, or 38% of product sales during the first quarter of 2010, compared to \$52.9 million, or 47% of product sales during the first quarter of 2009. The \$3.3 million decrease in blood screening product sales is primarily attributed to \$8.2 million of additional one-time revenue associated with the renegotiation of our collaboration agreement with Novartis recognized during the first quarter of 2009, partially offset by an increase in underlying blood screening product sales in the first quarter of 2010 resulting primarily from the contractual increase in the net percentage share of revenues we receive from Novartis, as well as an increase in the sale of blood screening related instrumentation.

Blood screening product sales were positively affected during the first quarter of 2010 as compared to the first quarter of 2009 by favorable estimated exchange rate impacts of \$1.2 million due to a weaker U.S. dollar.

Research products and services

As a result of our acquisition of Tepnel in April 2009, we have a new category of product sales, which we refer to as Research products and services. These sales represent outsourcing services for the pharmaceutical, biotechnology and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies. These sales totaled \$4.1 million during the first quarter of 2010.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|---------------------------------------|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Collaborative Research Revenue | \$ 3.3 | \$ 1.7 | \$ 1.6 | 94% |
| As a percent of total revenues | 2% | 1% | | |

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

The costs associated with collaborative research revenue are based on fully burdened full-time equivalent rates and are reflected in our consolidated statements of income under the captions Research and development, Marketing and sales and General and administrative, based on the nature of the costs. We do not separately track all of the costs applicable to our collaborations and, therefore, are not able to quantify all of the direct costs associated with collaborative research revenue.

Collaborative research revenue increased 94% during the first quarter of 2010 compared to the same period of 2009. This increase was primarily due to reimbursements from Novartis for shared development expenses, primarily attributable to the development of the PANTHER instrument for use in the blood screening market.

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

Table of Contents*(Dollars in millions)*

| | Three Months Ended March 31, | | | |
|------------------------------------|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Royalty and License Revenue | \$ 1.6 | \$ 2.0 | \$ (0.4) | (20)% |
| As a percent of total revenues | 1% | 2% | | |

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

Royalty and license revenue decreased 20% during the first quarter of 2010 compared to the same period of 2009, primarily as a result of lower royalties received from Novartis associated with the use of our technologies in the plasma screening 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.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|---|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Cost of Product Sales | \$ 42.7 | \$ 33.3 | \$ 9.4 | 28% |
| Gross profit margin as a percent of product sales | 67% | 70% | | |

Cost of product sales includes direct material, direct labor and manufacturing overhead associated with the production of inventories. Other components of cost of product sales include royalties, warranty costs, instrument and software amortization and allowances for scrap. Cost of product sales excludes the amortization of acquisition-related intangibles.

In addition, we manufacture significant quantities of materials, development lots, and clinical trial lots of product prior to receiving approval from the FDA for commercial sale. The majority of costs associated with development lots are classified as research and development, or R&D, expense. The portion of a development lot that is manufactured for commercial sale is capitalized to inventory and classified as cost of product sales upon shipment.

Cost of product sales increased 28% during the first quarter of 2010 compared to the same period of 2009. The \$9.4 million increase was primarily due to an additional \$7.6 million in cost of product sales as a result of our acquisitions of Tepnel and Prodesse and increases of \$3.5 million and \$0.8 million attributed to increased instrumentation and APTIMA shipments, respectively. These increased costs were partially offset by a \$1.6 million decrease in scrap transactions and \$1.3 million attributed to manufacturing variances related to changes in production volumes.

Our gross profit margin as a percentage of product sales decreased to 67% during the first quarter of 2010 compared to 70% during the first quarter of 2009. The decrease in gross profit margin as a percentage of product sales was principally attributed to lower overall gross margin percentages for the acquired Tepnel businesses, increased sales of lower margin instrumentation, and the favorable, non-recurring impact in 2009 of the renegotiated collaboration agreement with Novartis, which were partially offset by decreased scrap transactions.

Cost of sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales is also affected by manufacturing efficiencies, allowances for scrap or expired materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

A portion of our blood screening revenues is attributable to sales of TIGRIS instruments to Novartis, which totaled \$4.1 million and \$1.0 million during the first quarter of 2010 and 2009, respectively. Under our collaboration

Table of Contents

agreement with Novartis, we sell TIGRIS instruments to them at prices that approximate cost and share in profits of end-user sales in the United States. These instrument sales, therefore, negatively impact our gross margin percentage during the periods in which they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|--|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Acquisition-related Intangible Amortization | \$ 2.2 | \$ | \$ 2.2 | N/M |
| As a percent of total revenues | 2% | 0% | | |

Amortization expense related to our acquired intangible assets was \$2.2 million during the first quarter of 2010. Intangible assets are amortized using the straight-line method over their estimated useful lives, which range from 10 to 20 years. For details on the intangible assets acquired as part of our acquisitions of Tepnel and Prodesse, please refer to Note 2 Business combinations, of the Notes to the Consolidated Financial Statements included elsewhere in this report.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|---------------------------------|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Research and Development | \$ 29.7 | \$ 25.0 | \$ 4.7 | 19% |
| As a percent of total revenues | 22% | 22% | | |

We invest significantly in R&D as part of our ongoing efforts to develop new products and technologies. Our R&D expenses include the development of proprietary products and instrument platforms, as well as expenses related to the development of new products and technologies in collaboration with our partners. R&D spending is dependent on the status of projects under development and may vary substantially between quarterly or annual reporting periods.

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

R&D expenses increased 19% during the first quarter of 2010 compared to the same period of 2009. This increase was primarily due to the addition of Tepnel's and Prodesse's R&D expenses, increased spending for the development of the PANTHER platform, and expenses for the development of the Trichomonas, PCA3 and HPV assays.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|--------------------------------|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Marketing and Sales | \$ 14.8 | \$ 11.1 | \$ 3.7 | 33% |
| As a percent of total revenues | 11% | 10% | | |

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

Marketing and sales expenses increased 33% during the first quarter of 2010 compared to the same period of 2009. This increase is primarily attributed to the addition of Tepnel's and Prodesse's marketing and sales expenses, as well as

an increase in salaries and personnel-related expenses due to our continued investment in international expansion, primarily in Western Europe.

Table of Contents*(Dollars in millions)*

| | Three Months Ended March 31, | | | |
|-----------------------------------|-------------------------------------|-------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| General and Administrative | \$ 14.7 | \$ 13.8 | \$ 0.9 | 7% |
| As a percent of total revenues | 11% | 12% | | |

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 7% during the first quarter of 2010 compared to the same period of 2009. This increase is primarily attributed to the addition of Tepnel's and Prodesse's G&A expenses and increased legal fees related to ongoing litigation.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|----------------------------------|-------------------------------------|---------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Investment and interest income | \$ 3.9 | \$ 4.9 | \$ (1.0) | (20)% |
| Interest expense | (0.5) | (0.2) | (0.3) | 150% |
| Gain on contingent consideration | 1.7 | | 1.7 | N/M |
| Other expense, net | (0.2) | (0.1) | (0.1) | 100% |
| Total Other Income, Net | \$ 4.9 | \$ 4.6 | \$ 0.3 | 7% |

The decrease in investment and interest income during the first quarter of 2010 compared to the same period of 2009 is primarily attributed to \$2.2 million in net realized gains on sales of marketable securities, partially offset by decreased interest income due to lower investment balances in the current quarter as a result of the liquidation of investments to fund our recent acquisitions. We recorded an additional \$0.3 million of interest expense attributable to borrowings under our credit facility with Bank of America during the first quarter of 2010 as compared to the same period in 2009. The net increase in other expense during the first quarter of 2010 compared to the same period of 2009 was primarily attributable to exchange rate impacts.

During the first quarter of 2010, we recorded a \$1.7 million non-cash gain related to a reduction in the fair value of potential contingent consideration related to our acquisition of Prodesse. The range of potential contingent consideration that we may be required to pay is between \$0 and \$25.0 million. This range is tied to multiple performance measures including commercial and regulatory milestones. To the extent these milestones are earned, payments of up to \$25.0 million in total will be made, most likely between the third quarter of 2010 and the first quarter of 2012.

(Dollars in millions)

| | Three Months Ended March 31, | | | |
|-----------------------------------|-------------------------------------|----------------|----------------------|---------------------|
| | 2010 | 2009 | \$ Change | % Change |
| Income Tax Expense | \$ 12.1 | \$ 11.8 | \$ 0.3 | 3% |
| As a percent of income before tax | 33% | 31% | | |

The increase in our effective tax rate during the first quarter of 2010 compared to the same period of 2009 was largely due to lower tax-advantaged interest income, an expired federal research tax credit which has not been reauthorized in the current period and a one-time adjustment to the U.S. domestic manufacturing tax benefits in the prior period as a result of new guidance from the Internal Revenue Service, partially offset by adjustments to

contingent consideration that are generally not taxable and an increase in U.S. domestic manufacturing tax benefits.

We estimate that our annual effective tax rate for 2010 will be approximately 34% to 35%, but may be higher if the expired federal research tax credit is not reauthorized in 2010.

Table of Contents**Liquidity and Capital Resources**

| | March 31, 2010 | December 31, 2009 |
|--|-------------------------------|----------------------------------|
| | (In thousands, except ratio) | |
| Cash, cash equivalents and current marketable securities | \$ 460,883 | \$ 485,606 |
| Working capital | \$ 300,311 | \$ 330,749 |
| Current ratio | 2:1 | 2:1 |

Our working capital at March 31, 2010 decreased \$30.4 million from December 31, 2009 primarily due to the use of cash and investments to fund our two recent acquisitions and to repurchase shares under our share repurchase programs, partially offset by cash generated from operations.

The primary objectives of our investment policy are liquidity and safety of principal. Consistent with these objectives, investments are made with the goal of achieving the highest rate of return. The policy places emphasis on securities of high credit quality, with restrictions placed on maturities and concentration by security type and issue.

Our marketable securities include tax advantaged municipal securities and Federal Deposit Insurance Corporation, or FDIC, insured corporate bonds with a minimum Moody's credit rating of A3 or a Standard & Poor's credit rating of A-. As of March 31, 2010, we did not hold auction rate securities and have never held any such securities. Our investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At March 31, 2010, our portfolios had an average maturity of two years and an average credit quality of AA1 as defined by Moody's.

| | Three Months Ended March 31, | | |
|---|-------------------------------------|-------------|------------------|
| | 2010 | 2009 | \$ Change |
| | (In thousands) | | |
| Cash provided by (used in): | | | |
| Operating activities | \$ 40,687 | \$ 52,018 | \$ (11,331) |
| Investing activities | 58,086 | 39,141 | 18,945 |
| Financing activities | 7,508 | 135,000 | (127,492) |
| Purchases of property, plant and equipment (included in investing activities above) | (7,828) | (7,525) | 303 |

Our primary source of liquidity has been cash from operations, which includes the collection of accounts and other receivables related to product sales, collaborative research agreements, and royalty and license fees. Additionally, our liquidity was enhanced in 2009 by our credit facility with Bank of America, described in Note 7. Short-term borrowings, of the Notes to the Consolidated Financial Statements included elsewhere in this report. Our primary short-term cash needs, which are subject to change, include continued R&D spending to support new products, costs related to commercialization of products and purchases of instrument systems, primarily TIGRIS, for placement with our customers. In addition, we may use cash for strategic purchases which may include the acquisition of businesses and/or technologies complementary to our business. Certain R&D costs may be funded under collaboration agreements with our collaboration partners.

Operating activities provided net cash of \$40.7 million during the first quarter of 2010, primarily from net income of \$24.2 million and net non-cash charges of \$25.8 million, partially offset by an decrease in cash from operating assets and liabilities of \$9.3 million. Non-cash charges primarily consisted of income tax payable of \$10.7 million, depreciation of \$6.9 million, stock based compensation expense of \$5.9 million and amortization of intangibles of \$4.4 million.

Net cash provided by investing activities during the first quarter of 2010 was \$58.1 million. Cash used for purchases of property, plant and equipment totaled \$7.8 million, offset by \$68.0 million in net proceeds from the sale of marketable securities.

Net cash provided by financing activities during the first quarter of 2010 was \$7.5 million, primarily driven by \$16.9 million in proceeds from the issuance of our common stock, partially offset by \$11.0 million used to repurchase and retire approximately 233,200 shares of our common stock under our current stock repurchase program.

Table of Contents

We believe that our available cash balances, anticipated cash flows from operations, proceeds from stock option exercises and borrowings under our credit facility will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Further, debt financing may subject us to covenants restricting our operations. Because our current credit facility is secured by our marketable securities, any significant needs for cash may cause us to liquidate some or all of our marketable securities resulting in the need to partially or completely pay down our credit facility.

Contractual Obligations and Commercial Commitments

Our contractual obligations due as of March 31, 2010 were as follows (in thousands):

| | | Less than | | | More Than |
|---|------------|------------|--------------|--------------|--------------|
| | Total | 1 Year | 1-3 Years | 3-5 Years | 5 Years |
| Material purchase commitments ⁽¹⁾ | \$ 40,526 | \$ 29,793 | \$ 4,615 | \$ 4,119 | \$ 1,999 |
| Operating leases ⁽²⁾ | 7,212 | 1,778 | 3,157 | 2,214 | 63 |
| Collaborative commitments ⁽³⁾ | 4,768 | 771 | 1,921 | 750 | 1,326 |
| Minimum royalty commitments ⁽⁴⁾ | 16,527 | 1,282 | 3,170 | 3,840 | 8,235 |
| Deferred employee compensation ⁽⁵⁾ | 3,582 | 696 | 1,557 | 869 | 460 |
| Capital leases ⁽⁶⁾ | 518 | 248 | 250 | 20 | |
| Contingent consideration ⁽⁷⁾ | 16,249 | 14,172 | 2,077 | | |
| Credit facility ⁽⁸⁾ | 241,846 | 241,846 | | | |
| Total ⁽⁹⁾ | \$ 331,228 | \$ 290,586 | \$ 16,747 | \$ 11,812 | \$ 12,083 |

⁽¹⁾ Amounts represent our minimum purchase commitments from key vendors for the TIGRIS, PANTHER, Luminex and Cepheid instruments, as well as raw materials used in manufacturing. Of the \$40.5 million total, \$20.3 million is expected to be used to purchase

T I G R I S
instruments, of
w h i c h w e
anticipate that
approximately
\$12.1 million of
instruments will
b e s o l d t o
Novartis. Not
included in the
\$40.5 million is
\$6.6 million
expected to be
used to purchase
pre-production
and production
P A N T H E R
instruments, and
a s s o c i a t e d
t o o l i n g ,
pursuant to our
development
agreement with
S t r a t e c
B i o m e d i c a l
Systems AG, or
Stratec, as well
as potential
m i n i m u m
p u r c h a s e
commitments
u n d e r o u r
s u p p l y
agreement with
Stratec. Our
o b l i g a t i o n s
under the supply
agreement are
contingent on
s u c c e s s f u l
completion of
all activities
u n d e r o u r
development
agreement with
Stratec.

- (2) R e f l e c t s
obligations for
facilities and
vehicles under

operating leases in place as of March 31, 2010. Future minimum lease payments are included in the table above.

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

(4) Amounts represent our minimum royalties due on the net sales of products incorporating licensed technology and subject to a minimum annual royalty payment. During the three

months ended March 31, 2010, we recorded \$2.6 million in royalty costs related to our various license agreements.

- (5) We have liabilities for deferred employee compensation which totaled \$5.4 million at March 31, 2010. Under our deferred compensation plan, participants may elect in-service distributions on specified future dates, or a distribution upon retirement. Of the \$5.4 million, \$1.8 million is payable upon employee retirement and as such was not included in the table above as we cannot reasonably predict when a retirement event may occur. Total liabilities for deferred employee compensation are offset by deferred compensation assets, which totaled

\$5.8 million at March 31, 2010.

- (6) Reflects obligations on capital leases in place as of March 31, 2010. Interest amounts were not material, therefore, capital lease obligations are shown net of interest expense in the table above.
- (7) Represents the aggregate fair value of the payments we may be obligated to make to former Prodesse securityholders. This amount is reflected in our consolidated balance sheets under the captions Other accrued expenses and Other long-term liabilities.
- (8) As of March 31, 2010, the total principal amount outstanding under our revolving credit facility with Bank of America was \$240.0 million. The term of this

credit facility is due to expire in February 2011. Interest payable on this outstanding amount included in the table above has been estimated based on the interest rate payable at March 31, 2010, which was 0.8287%. 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. In addition, we are required to pay interest and fees on the undrawn sub-limit for the issuance of letters of credit under the credit

facility of up to \$10.0 million, which has also been estimated for the remaining term of the credit facility based on the fixed rate of 0.25% at March 31, 2010.

Table of Contents

(9) Does not include amounts relating to our obligations under our collaboration with Novartis, pursuant to which both parties have obligations to each other. Under our collaboration agreement with Novartis, we are obligated to manufacture and supply blood screening assays to Novartis, and Novartis is obligated to purchase all of the assay quantities specified on a 90-day demand forecast, due 90 days prior to the date Novartis intends to take delivery, and certain quantities specified on a rolling 12-month forecast.

Liabilities associated with uncertain tax positions, currently estimated at \$7.7 million (including interest), are not included in the table above as we cannot reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

Off-Balance Sheet Arrangements

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

relationships.

Available Information

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our investment portfolio and the amount of interest payable on our senior secured revolving credit facility with Bank of America. As of March 31, 2010, the total principal amount outstanding under the revolving credit facility was \$240.0 million. At our option, loans accrue interest at a per annum rate based on, either: the base rate (the base rate is defined as the greatest of (i) the federal funds rate plus a margin equal to 0.50%, (ii) Bank of America's prime rate and (iii) LIBOR plus a margin equal to 1.00%); or LIBOR plus a margin equal to 0.60%, in each case for interest periods of 1, 2, 3 or 6 months as selected by us. We do not believe that we are exposed to significant interest rate risk with respect to our credit facility based on our option to select the rate at which interest accrues under the credit facility, the short-term nature of the borrowings and our ability to pay off the outstanding balance in a timely manner if the applicable interest rate under the credit facility increases above the current interest rate yields on our investment portfolio. A 100 basis point increase or decrease in interest rates would increase or decrease our interest expense by approximately \$2.4 million on an annual basis.

Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in investment grade securities with an average portfolio maturity of no more than three years. A 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately \$10.2 million on an annual basis. While changes in interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our consolidated statements of income until the investment is sold or if a reduction in fair value is determined to be other-than-temporary.

Table of Contents***Foreign Currency Exchange Risk***

Although the majority of our revenue is realized in U.S. dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. We translate the financial statements of our non-U.S. operations using the end-of-period exchange rates for assets and liabilities and the average exchange rates for each reporting period for results of operations. Net gains and losses resulting from the translation of foreign financial statements and the effect of exchange rates in intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders' equity under the caption "Accumulated other comprehensive income." These adjustments will affect net income upon the sale or liquidation of the underlying investment.

Under our collaboration agreement with Novartis, a growing portion of blood screening product sales is from western European countries. As a result, our international blood screening product sales are affected by changes in the foreign currency exchange rates of those countries where Novartis' business is conducted in Euros or other local currencies. Based on international blood screening product sales during the first quarter of 2010, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately \$4.8 million annually. Similarly, a 10% movement of currency exchange rates would result in a diagnostic product sales increase or decrease of approximately \$3.5 million annually. Our exposure for both blood screening and diagnostic product sales is primarily in the U.S. dollar versus the Euro, British pound, Australian dollar, and Canadian dollar.

Our total payables denominated in foreign currencies as of March 31, 2010 were not material. Our receivables by currency as of March 31, 2010 reflected in U.S. dollar equivalents were as follows (in thousands):

| | |
|---|---------------|
| U.S. dollar | \$ 37,748 |
| Euro | 4,683 |
| British pound | 3,023 |
| Canadian dollar | 1,362 |
| Danish krone | 257 |
| Czech koruna | 212 |
| Swiss franc | 18 |
| Total gross trade accounts receivable | \$ 47,303 |

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

We did not enter into any foreign currency forward contracts during the three months ended March 31, 2010.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures and internal controls that are designed to ensure that information required to be disclosed in our current and periodic reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures and internal controls, management recognized that any controls and procedures, no matter how well designed and

operated, can provide only reasonable and not absolute assurance of achieving the desired

Table of Contents

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, 2010.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation has included certain internal control areas in which we have made and are continuing to make changes to improve and enhance controls.

There have been no changes in our internal control over financial reporting during the three months ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As of the date of this report, we have not completed our assessment of Prodesse's internal control over financial reporting. As a result, we have excluded Prodesse from the evaluation of our internal control over financial reporting contained in this report.

PART II OTHER INFORMATION**Item 1. Legal Proceedings**

A description of our material pending legal proceedings is disclosed in Note 9 – Contingencies, of the Notes to the Consolidated Financial Statements included elsewhere in this report and is incorporated by reference herein. We are also engaged from time to time in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. If any of these matters were resolved in a manner unfavorable to us, our business, financial condition and results of operations would be harmed.

Item 1A. Risk Factors

Set forth below and elsewhere in this quarterly report on Form 10-Q, and in other documents we file with the SEC, are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones we face. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition. We have marked with an asterisk those risk factors that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2009.

Our quarterly revenue and operating results may vary significantly in future periods and our stock price may decline.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenues are unpredictable and may fluctuate due to changes in demand for our products, including fluctuations in demand for blood screening tests from our blood screening collaboration partner Novartis, the timing of acquisitions, the

Table of Contents

execution of customer contracts, the receipt of milestone payments, or the failure to achieve and receive the same, and the initiation or termination of corporate collaboration agreements. In addition, a significant portion of our costs can also vary substantially between quarterly or annual reporting periods. For example, the total amount of research and development costs in a period often depends on the amount of costs we incur in connection with manufacturing developmental lots and clinical trial lots. Moreover, a variety of factors may affect our ability to make accurate forecasts regarding our operating results. For example, certain of our products have a relatively limited sales history, which limits our ability to accurately project future sales, prices and related sales cycles. In addition, we base our internal projections of blood screening product sales and international sales of various diagnostic products on projections prepared by our distributors of these products and therefore we are dependent upon the accuracy of those projections. We expect continuing fluctuations in our manufacture and shipment of blood screening products to Novartis, which vary each period based on Novartis' inventory levels and supply chain needs. In addition, our respiratory infectious disease product line is subject to significant seasonal fluctuations. Because of all of these factors, our operating results in one or more future quarters may fail to meet or exceed financial guidance we may provide from time to time and the expectations of securities analysts or investors, which could cause our stock price to decline. In addition, the trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about our business and that of our competitors. Furthermore, failure to achieve our operational goals may inhibit our targeted growth plans and the successful implementation of our strategic objectives.

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

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

We are dependent on Novartis and other third parties for the distribution of some of our products. If any of our distributors terminates its relationship with us or fails to adequately perform, our product sales will suffer.

We rely on Novartis to distribute blood screening products we manufacture. Commercial product sales to Novartis accounted for 37% of our total revenues during the first quarter of 2010 and 40% of our total revenues for 2009. In January 2009, we extended the term of our blood screening collaboration with Novartis to June 30, 2025, subject to earlier termination under certain limited circumstances specified in the collaboration agreement. In addition, we supply our transcription-mediated amplification, or TMA, assay for the qualitative detection of HCV and analyte specific reagents, or ASRs, for the quantitative detection of HCV to Siemens Healthcare Diagnostics, Inc., or Siemens, pursuant to a collaboration agreement.

We rely upon bioMérieux S.A., or bioMérieux, for distribution of certain of our products in most of Europe and Australia, Fujirebio, Inc., or Fujirebio, for distribution of certain of our products in Japan, and various independent distributors for distribution of our products in other regions. Distribution rights revert back to us upon termination of the distribution agreements. Our distribution agreements with Fujirebio and bioMérieux expire in December 2010 and May 2012, respectively, although each agreement may terminate earlier under certain circumstances.

If any of our distribution or marketing agreements is terminated, particularly our collaboration agreement with Novartis, or if we elect to distribute new products directly, we will have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to successfully market

our products, our product sales will decrease.

Table of Contents

If we cannot maintain our current corporate collaborations and enter into new corporate collaborations, our product development could be delayed. In particular, any failure by us to maintain our blood screening collaboration with Novartis would have a material adverse effect on our business.

We rely, to a significant extent, on our corporate collaborators for funding development and for marketing certain of our products. In addition, we expect to rely on our corporate collaborators for the commercialization of certain products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. We cannot control the amount and timing of resources our corporate collaborators devote to our programs or potential products.

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

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

If any of our current collaboration agreements is terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to devote additional internal resources to product development or marketing or to terminate some development programs or seek alternative corporate collaborations. We may not be able to negotiate additional corporate collaborations on acceptable terms, if at all, and these collaborations may not be successful. In addition, in the event of a dispute under our current or any future collaboration agreements, such as those under our agreements with Novartis and Siemens, a court or arbitrator may not rule in our favor and our rights or obligations under an agreement subject to a dispute may be adversely affected, which may have an adverse effect on our business or operating results.

We may acquire other businesses or form collaborations, strategic alliances and joint ventures that could decrease our profitability, result in dilution to stockholders or cause us to incur debt or significant expense, and acquired companies or technologies could be difficult to integrate and could disrupt our business.

As part of our business strategy, we intend to pursue acquisitions of complementary businesses and enter into technology licensing arrangements. We also intend to pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. We have limited experience in acquiring other companies. Any future acquisitions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company may also require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all.

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

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

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

- the inability to retain or replace key employees of any acquired businesses or hire enough qualified personnel to staff any new or expanded operations;

Table of Contents

the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;

the exposure to federal, state, local and foreign tax liabilities in connection with any acquisition or the integration of any acquired businesses;

the exposure to unknown liabilities;

higher than expected acquisition and integration costs that could cause our quarterly and annual operating results to fluctuate;

increased amortization expenses if an acquisition includes significant intangible assets;

combining the operations and personnel of acquired businesses with our own, which could be difficult and costly;

the risk of entering new markets; and

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

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

Our future success will depend in part upon our ability to enhance existing products and to develop, introduce and commercialize new products.

The markets for our products are characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete. Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products. We believe that we will need to continue to provide new products that can detect and quantify a greater number of organisms from a single sample. We also believe that we must develop new assays that can be performed on automated instrument platforms. The development of new instrument platforms, if any, in turn may require the modification of existing assays for use with the new instrument, and additional time-consuming and costly regulatory approvals. For example, our failure to successfully develop and commercialize our development-stage PANTHER instrument system on a timely basis could have a negative impact on our financial performance.

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological, market and medical practice trends, as well as precise technological execution. In addition, the successful development of new products will depend on the development of new technologies. We may be required to undertake time-consuming and costly development activities and to seek regulatory approval for these new products. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of these new products. We have experienced delays in receiving FDA clearance in the past. Regulatory clearance or approval of any new products we may develop may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and these and other new products may not be successfully commercialized. Failure to timely achieve regulatory approval for our products and introduce products to market could negatively affect our growth objectives and financial performance.

In October 2006 and May 2007, the FDA granted marketing approval for use of the Procleix Ultrio assay on our enhanced semi-automated system, or eSAS, and TIGRIS, respectively, to screen donated blood, plasma, organs and

tissue for HIV-1 and HCV in individual blood donations or in pools of up to 16 blood samples. In August 2008, the FDA approved the Procleix Ultrio assay to also screen donated blood, plasma, organs and tissues for HBV in individual blood donations or in pools of up to 16 blood samples on eSAS and the TIGRIS system. However, the FDA's current requirements for testing blood donations do not mandate testing for HBV deoxyribonucleic acid, or DNA. At its April 2009 meeting, the FDA's Blood Products Advisory Committee, or BPAC, considered various issues concerning HBV NAT testing of donated blood. Although we believe the BPAC discussion supported the

Table of Contents

utility of NAT testing for HBV, no formal recommendation was made to make such testing mandatory at the meeting. We believe blood screening centers will continue to focus on improving the safety of donated blood by adopting the most advanced blood screening technologies available. For example, we believe most of our U.S. blood screening customers have already adopted the Procleix Ultrio assay, even in the absence of an FDA mandate. However, if some customers do not transition to the use of the Procleix Ultrio assay at expected levels for any of these or other reasons, our financial performance may be adversely affected.

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., bioMérieux, and Hologic, Inc., currently compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. Our existing competitors or new market entrants may be in better position than we are to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners. Many of our competitors have, and in the future these and other competitors may have, significantly greater financial, marketing, sales, manufacturing, distribution and technological resources than we do. Moreover, these companies may have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do, any of which may adversely affect our customer retention and market share.

Competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue or market acceptance. Some of our competitors have developed real time or kinetic nucleic acid assays and semi-automated instrument systems for those assays. Additionally, some of our competitors are developing assays that permit the quantitative detection of multiple analytes (or quantitative multiplexing). Although we are evaluating and/or developing such technologies, we believe some of our competitors are further along in the development process than we are with respect to such assays and instrumentation.

In the market for blood screening products, the primary competitor to our collaboration with Novartis is Roche, which received FDA approval of its PCR-based NAT tests for blood screening in December 2002 and received FDA approval of a multiplex real-time PCR assay to screen donated blood in December 2008. Our collaboration with Novartis also competes with blood banks and laboratories that have internally developed assays based on PCR technology, Ortho-Clinical Diagnostics, Inc., a subsidiary of Johnson & Johnson that markets an HCV antigen assay, and Abbott and Siemens with respect to immunoassay products. In the future, our collaboration blood screening products also may compete with viral inactivation or reduction technologies and blood substitutes.

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

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

Table of Contents

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 are currently involved in proceedings with Digene Corporation, or Digene (now Qiagen Gaithersburg, Inc.), regarding our supply and purchase agreement with Roche Molecular Systems. In December 2006, Digene filed a demand for binding arbitration against Roche with the International Centre for Dispute Resolution, or ICDR, that asserted, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and sought a determination that the supply and purchase agreement is null and void. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. The ruling issued by the ICDR in 2009 rejected all claims asserted by Digene and granted our motion to recover attorneys' fees and costs from Digene in the amount of approximately \$2.9 million. We filed a petition to confirm the arbitration award in the U.S. District Court for the Southern District of New York and Digene filed a petition to vacate or modify the award. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued.

Table of Contents

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. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.

We have no firm long-term commitments from KMC Systems, MGM Instruments or any of our other manufacturers to supply products to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order. If KMC Systems, MGM Instruments or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its manufacturing operations or becomes insolvent, then instrument shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation. Further, because we place orders with our manufacturers based on forecasts of expected demand for our instruments, if we inaccurately forecast demand we may be unable to obtain adequate manufacturing capacity or adequate quantities of components to meet our customers' delivery requirements, or we may accumulate excess inventories.

We may in the future need to find new contract manufacturers to increase our volumes or to reduce our costs. We may not be able to find contract manufacturers that meet our needs, and even if we do, qualifying a new contract manufacturer and commencing volume production is expensive and time consuming. For example, we believe qualifying a new manufacturer of our TIGRIS instrument would take approximately 12 months. If we are required or elect to change contract manufacturers, we may lose revenues and our customer relationships may suffer.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in commercializing, or be unable to commercialize, our products as a result of, these regulations.

The clinical diagnostic and blood screening products we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. We generally are prohibited from marketing our clinical diagnostic products in the United States unless we obtain either 510(k) clearance or premarket approval from the FDA. Delays in receipt of, or failure to obtain, clearances or approvals for future products could delay or preclude realization of product revenues from new products or result in substantial additional costs which could decrease our profitability.

Outside the United States, our ability to market our products is contingent upon maintaining our certification with the International Organization for Standardization, and in some cases receiving specific marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. Our European Union, or EU, foreign marketing authorizations cover all member states. Foreign registration is an ongoing process as we register additional products and/or product modifications.

The process of seeking and obtaining regulatory approvals, particularly from the FDA and some foreign governmental authorities, to market our products can be costly and time consuming, and approvals might not be granted for future products on a timely basis, if at all. In March 2008, we started U.S. clinical trials for our investigational APTIMA HPV assay. If we experience unexpected complications in conducting the trial, we may incur additional costs or experience delays or difficulties in receiving FDA approval. For example, we originally expected that enrollment and testing of approximately 7,000 women would be required to complete this trial. However, we actually enrolled approximately 13,000 women in the trial based on the actual prevalence of cervical disease observed. Although we completed enrollment in the trial late in 2009, we cannot provide any assurances that the FDA will ultimately approve the use of our APTIMA HPV assay upon completion of the trial. Failure to obtain or delay in obtaining FDA approval of our APTIMA HPV assay could have a material adverse effect on our financial performance. In the third quarter of 2009, we began studies to validate our APTIMA *Trichomonas vaginalis* assay on the TIGRIS instrument system to permit registration and sale of the assay in the EU, as well as commenced a U.S.

clinical trial for the *Trichomonas* assay on the TIGRIS instrument system. We cannot provide any assurances that this assay will be cleared for sale. In addition, we commenced a U.S. clinical trial in the third

Table of Contents

quarter of 2009 for our CE-marked PROGENSA PCA3 assay; however, there can be no assurance that this assay will be approved for sale in the United States.

We are also required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product. These requirements include, among other things, the Quality System Regulation, labeling requirements, the FDA's general prohibition against promoting products for unapproved or off-label uses and adverse event reporting regulations. Failure to comply with applicable FDA product regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications and criminal prosecution. Any of these actions, in combination or alone, could prevent us from selling our products and harm our business.

Certain assay reagents may be sold in the United States as ASRs without 510(k) clearance or premarket approval from the FDA. However, the FDA restricts the sale of these ASR products to clinical laboratories certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments, or CLIA, and also restricts the types of products that can be sold as ASRs. In addition, each laboratory must validate the ASR product for use in diagnostic procedures as a laboratory developed test. We currently offer several ASR products including ASRs for use in the detection of PCA3 mRNA and for use in the detection of the parasite *Trichomonas vaginalis*. We also have developed an ASR for quantitative HCV testing that Siemens provides to Quest Diagnostics Incorporated. In September 2007, the FDA published guidance that defines the types of products that can be sold as ASRs. Under the terms of this guidance and the ASR Manufacturer Letter issued in June 2008 by the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA, it may be more challenging for us to market some of our ASR products and we may be required to terminate those ASR product sales, conduct clinical studies and make submissions of our ASR products to the FDA for clearance or approval.

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

As both the FDA and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Complying with these rules and regulations could cause us to incur significant additional expenses and delays in launching products, which would harm our operating results.

Our products are subject to recalls even after receiving FDA approval or clearance.

The FDA and governmental bodies in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to product manufacturing, quality, labeling, advertising, or promotional activities, or if new information is obtained concerning the safety of a product. Our assay products incorporate complex biochemical reagents and our instruments comprise complex hardware and software. We have in the past voluntarily recalled products, which, in each case, required us to identify a problem and correct it. In December 2008, we recalled certain AccuProbe test kits after receiving a customer complaint indicating the customer had received a kit containing a probe reagent tube that appeared upon visual inspection to be empty. We confirmed that a manufacturing error had occurred, corrected the problem, recalled all potentially affected products, provided replacements and notified the FDA and other appropriate authorities.

Although none of our past product recalls had a material adverse effect on our business, our products may be subject to a future government-mandated recall or a voluntary recall, and any such recall could divert managerial and financial resources, could be more difficult and costly to correct, could result in the suspension of sales of our products and could harm our financial results and our reputation.

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

We currently receive revenues from the sale of blood screening assays primarily for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test. Since Novartis sells blood screening assays under our collaboration to blood screening centers on a per donation basis, our profit margins are greater when a single test can be used to screen multiple donor samples.

We believe certain blood screening markets are trending from pooled testing of large numbers of donor samples to smaller pool sizes. A greater number of tests will be required in markets where smaller pool sizes are required. Under our amended and restated collaboration agreement with Novartis, we bear half of the cost of manufacturing blood screening assays. The greater number of tests required for smaller pool sizes will increase our variable manufacturing costs, including costs of raw materials and labor. If the price per donor or total sales volume does not increase in line with the increase in our total variable manufacturing costs, our gross profit margin percentage from sales of blood screening assays will decrease upon adoption of smaller pool sizes. We have already observed this trend with respect to certain sales internationally. We are not able to predict accurately the ultimate extent to which our gross profit margin percentage will be negatively affected as a result of smaller pool sizes, because we do not know the ultimate selling price that Novartis would charge to the end user or the degree to which smaller pool size testing will be adopted across the markets in which our products are sold.

Because we depend on a small number of customers for a significant portion of our total revenues, the loss of any of these customers or any cancellation or delay of a large purchase by any of these customers could significantly reduce our revenues.

Historically, a limited number of customers has accounted for a significant portion of our total revenues, and we do not have any long-term commitments with these customers, other than our collaboration agreement with Novartis. Total revenues from our blood screening collaboration with Novartis, which include product sales, collaborative research revenues and royalties, accounted for 39% of our revenues during the first quarter of 2010 and 42% of our total revenues for 2009. Our blood screening collaboration with Novartis is largely dependent on two large customers in the United States, The American Red Cross and America's Blood Centers, although we do not receive any revenues directly from those entities. Novartis was our only customer that accounted for greater than 10% of total revenues during the first quarter of 2010. However, various state and city public health agencies accounted for an aggregate of 7% of our revenues during the first quarter of 2010 and 8% of our total revenues for 2009. Although state and city public health agencies are legally independent of each other, we believe they tend to act similarly with respect to their product purchasing decisions. We anticipate that our operating results will continue to depend to a significant extent upon revenues from a small number of customers. The loss of any of our key customers, or a significant reduction in sales volume or pricing to those customers, could significantly reduce our revenues.

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

Our success will depend in part on our ability to obtain patent protection for, or maintain the secrecy of, our proprietary products, processes and other technologies for the development of blood screening and clinical diagnostic products and instruments. Although we had more than 510 U.S. and foreign patents covering our products and technologies as of March 31, 2010, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. Our existing patents will expire by December 15, 2028 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.

Table of Contents

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.

Recently, we have been involved in a number of patent-related disputes with third parties. In December 2006, Digene (now Qiagen Gaithersburg, Inc.) filed a demand for binding arbitration against Roche with the ICDR that asserted, among other things, that Roche materially breached a cross-license agreement between Roche and Digene by granting us an improper sublicense and sought a determination that our supply and purchase agreement with Roche is null and void. In July 2007, the ICDR arbitrators granted our petition to join the arbitration. The ruling issued by the ICDR in 2009 rejected all claims asserted by Digene and granted our motion to recover attorneys' fees and costs from Digene in the amount of approximately \$2.9 million. We filed a petition to confirm the arbitration award in the U.S. District Court for the Southern District of New York and Digene filed a petition to vacate or modify the award. A hearing on the petitions was held in December 2009 and a ruling has not yet been issued.

In October 2009, we filed a patent infringement action against BD in the U.S. District Court for the Southern District of California. The complaint alleges that BD's Viper[™] XTR[™] testing system infringes five of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint also alleges that BD's ProbeT[™] Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA assays used with the Viper XTR testing system infringe two of our

U.S. patents covering penetrable caps for specimen collection tubes. Finally, the complaint alleges that BD has infringed our U.S. patent on methods and kits for destroying the ability of a nucleic acid to be amplified. The complaint seeks monetary damages and injunctive relief. In March 2010, we filed a second complaint for patent infringement against BD in the U.S. District Court for the Southern District of California. The

Table of Contents

complaint alleges that BD's BD MAX System[®] (formerly known as the HandyLab Jaguar system) infringes four of our U.S. patents covering automated processes for preparing, amplifying and detecting nucleic acid targets. The complaint seeks monetary damages and injunctive relief. There can be no assurances as to the final outcome of this litigation.

Pursuant to our collaboration agreement with Novartis, we hold certain rights in the blood screening and clinical diagnostics fields under patents originally issued to Novartis covering the detection of HIV. We sell a qualitative HIV test in the clinical diagnostics field and we manufacture tests for HIV for use in the blood screening field, which Novartis sells under Novartis' brands and name. In February 2005, the U.S. Patent and Trademark Office declared two interferences related to U.S. Patent No. 6,531,276 (Methods For Detecting Human Immunodeficiency Virus Nucleic Acid), originally issued to Novartis. The first interference was between Novartis and the National Institutes of Health, or NIH, and pertained to U.S. Patent Application No. 06/693,866 (Cloning and Expression of HTLV-III DNA). The second interference was between Novartis and Institut Pasteur, and pertained to Institut Pasteur's U.S. Patent Application No. 07/999,410 (Cloned DNA Sequences, Hybridizable with Genomic RNA of Lymphadenopathy-Associated Virus (LAV)). We are informed that the Patent and Trademark Office determined that Institut Pasteur invented the subject matter at issue prior to NIH and Novartis. We are also informed that Novartis and NIH subsequently filed actions in the U.S. District Court for the District of Columbia challenging the decisions of the Patent and Trademark Office in the patent interference cases. From November 2007 through September 2008, the parties engaged in settlement negotiations and then notified the court that they had signed a memorandum of understanding prior to the negotiation of final, definitive settlement documents. In May 2008, we signed a license agreement with Institut Pasteur concerning Institut Pasteur's intellectual property for the molecular detection of HIV, covering products manufactured and sold through, and under, our brands or name. In September 2008, the parties to the pending litigation in the U.S. District Court for the District of Columbia informed the court that they were unable to reach a final, definitive agreement and intended to proceed with litigation. There can be no assurances as to the ultimate outcome of the interference litigation and no assurances as to how the outcome of the interference litigation may affect the patent rights we licensed from Institut Pasteur, or Novartis' right to sell HIV blood screening tests.

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

Comprehensive health care reform legislation has been signed into law in the United States. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of our assays and instruments. This tax is scheduled to take effect in 2013. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance and an increased focus on preventive medicine, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through spending cuts or other actions are unsuccessful, the increased tax burden would adversely effect 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. In March 2009, we and Bank of America amended the credit facility to increase the amount which we may borrow from time to time under the credit agreement from \$180.0 million to \$250.0 million. In April 2009, we borrowed an additional \$70.0 million under the revolving credit facility, bringing the total principal amount outstanding under the credit facility to \$240.0 million as of March 31, 2010. In February 2010, our credit agreement with Bank of America was amended to extend the maturity date to February 2011.

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

increase our vulnerability to general adverse economic and industry conditions;

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

Table of Contents

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

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

As of March 31, 2010, we had approximately \$462.4 million of long-lived assets, including \$13.0 million of capitalized software, net of accumulated amortization, relating to our TIGRIS and PANTHER instruments, goodwill of \$122.2 million, a \$5.4 million investment in Qualigen, Inc., or Qualigen, a \$5.0 million investment in DiagnoCure, Inc., or DiagnoCure, a \$0.7 million investment in Roka Bioscience, Inc., or Roka, and \$158.0 million of capitalized licenses and manufacturing access fees, patents, purchased intangibles and other long-term assets. Additionally, we had \$71.6 million of land and buildings, \$22.5 million of building improvements, \$63.7 million of equipment and furniture and fixtures and \$0.3 million in construction in progress. The substantial majority of our long-lived assets are located in the United States. The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable.

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

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

A change in accounting standards or practices, or a change in existing taxation rules or practices, can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. Our effective tax rate can also be impacted by changes in estimates of prior years' items, past and future levels of research and development spending, the outcome of audits by federal, state and foreign jurisdictions and changes in overall levels of income before tax.

We expect to continue to incur significant research and development expenses, which may reduce our profitability.

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

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

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

We may not have financing for future capital requirements, which may prevent us from addressing gaps in our product offerings or improving our technology.

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

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

Table of Contents

required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products we and our distributors require, which could harm our business and results of operations.

Significant additional work will be required for scaling-up manufacturing of each new product prior to commercialization, and we may not successfully complete this work. Manufacturing and quality control problems have arisen and may arise in the future as we attempt to scale-up our manufacturing of a new product, and we may not achieve scale-up in a timely manner, at a commercially reasonable cost or at all. In addition, although we expect some of our newer products and products under development to share production attributes with certain of our existing products, production of these newer products may require the development of new manufacturing technologies and expertise. We may be unable to develop the required technologies or expertise.

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

Blood screening and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States and the EU, certain products may also require individual lot release testing. Maintaining compliance with multiple regulators, and multiple centers within the FDA, adds complexity and cost to our overall manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies, and these facilities are subject to Quality System Regulations requirements of the FDA. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 27% of our revenues during the first quarter of 2010 and 26% of our total revenues for 2009. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 57% of our international revenues during the first quarter of 2010 and 60% of our total international revenues for 2009.

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

Table of Contents

In addition, we anticipate that requirements for smaller pool sizes of blood samples will result in lower gross margin percentages, as additional tests are required to deliver the sample results. We have already observed this trend with respect to certain sales in Europe. In general, international pool sizes are smaller than domestic pool sizes and, therefore, growth in blood screening revenues attributed to international expansion has led and we expect that it will continue to lead to lower gross margin percentages.

If third-party payors do not reimburse our customers for the use of our clinical diagnostic products or if they reduce reimbursement levels, our ability to sell our products will be harmed.

We sell our clinical diagnostic products primarily to large reference laboratories, public health institutions and hospitals, substantially all of which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other government programs, private insurance plans and managed care programs. Most of these third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors may also refuse to reimburse for experimental procedures and devices.

Third-party payors' reimbursement policies may affect sales of our products that screen for more than one pathogen at the same time, such as our APTIMA Combo 2 product for screening for the causative agents of chlamydial infections and gonorrhea in the same sample. Third-party payors may choose to reimburse our customers on a per test basis, rather than on the basis of the number of results given by the test. This may result in our customers electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, these entities likely would purchase separate tests for each disease, rather than products that test for more than one microorganism.

In addition, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and price levels of our products. If our customers are not reimbursed for our products, they may reduce or discontinue purchases of our products, which would cause our revenues to decline.

We are dependent on technologies we license, and if we fail to maintain our licenses or license new technologies and rights to particular nucleic acid sequences for targeted diseases in the future, we may be limited in our ability to develop new products.

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

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

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

Table of Contents

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

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

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

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

We manufacture substantially all of our products in four manufacturing facilities, two of which are located in San Diego, California and the others are located in Stamford, Connecticut and Waukesha, Wisconsin. These facilities and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. Our facilities may be harmed by natural or man-made disasters, including, without limitation, earthquakes, tornadoes and fires, and in the event they are affected by a disaster, we would be forced to rely on third-party manufacturers. The wildfires in San Diego in October 2007 required that we temporarily shut down our facility for the manufacture of blood screening products. In the event of a disaster, we may lose customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.

Our research and development activities and our manufacturing activities involve the controlled use of infectious agents, potentially harmful biological materials, as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury, and we could be held liable for damages that result from any contamination or injury. In addition, we are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The damages resulting from any accidental contamination and the cost of compliance with environmental laws and regulations could be significant.

The anti-takeover provisions of our certificate of incorporation and bylaws, and provisions of Delaware law, could delay or prevent a change of control that our stockholders may favor.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or other change of control that our stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management. The provisions of our amended and restated certificate of incorporation and amended and restated bylaws, among other things:

divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms;

limit the right of stockholders to remove directors;

Table of Contents

regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders; and

authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

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

If we do not effectively manage our growth, it could affect our ability to pursue opportunities and expand our business.

Growth in our business has placed and may continue to place a significant strain on our personnel, facilities, management systems and resources. We will need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce. In addition, we will have to maintain close coordination among our various departments and locations. If we fail to effectively manage our growth, it could adversely affect our ability to pursue business opportunities and expand our business.

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

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we 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 could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flow and to otherwise operate our business, 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, 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.

Table of Contents**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 2010:

| | Total Number of Shares Purchased | Average Price Paid Per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs |
|-------------------------------------|---|---|---|---|
| January 1-31, 2010 | | \$ | | \$ 100,000,000 |
| February 1-28, 2010 | 38,000 | 44.65 | 38,000 | 98,303,436 |
| March 1-31, 2010 | 196,040 | 47.46 | 195,200 | 89,039,428 |
| Total ⁽¹⁾ ⁽²⁾ | 234,040 | 47.00 | 233,200 | |

(1) In February 2010, our Board of Directors authorized the repurchase of up to \$100.0 million of our common stock over the one year period following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. As of

March 31, 2010, we repurchased 233,200 shares under this program at an average price of \$47.00.

- (2) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced plans or programs is due to the shares of common stock withheld by us for the payment of taxes upon vesting of certain employees restricted stock. During the first quarter of 2010, we repurchased and retired 840 shares of our common stock, at an average price of \$46.77, withheld by us to satisfy employee tax obligations upon vesting of restricted stock granted under our 2003 Incentive Award Plan. We may make similar repurchases in the future to satisfy

employee tax obligations upon vesting of restricted stock. As of March 31, 2010, we had an aggregate of 247,711 shares of restricted stock and 60,000 shares of deferred issuance restricted stock awards outstanding.

Table of Contents

Item 6. Exhibits

Exhibit

Number

Description

| | |
|-----------|--|
| 2.1(1) | Agreement and Plan of Merger, dated as of October 6, 2009, by and among Gen-Probe Incorporated, Prodigy Acquisition Corp., Prodesse, Inc. and Thomas M. Shannon and R. Jeffrey Harris, as the Securityholders Representative Committee.* |
| 3.1(2) | Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated. |
| 3.2(3) | Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated. |
| 3.3(4) | Amended and Restated Bylaws of Gen-Probe Incorporated. |
| 3.4(5) | Certificate of Elimination of Series A Junior Participating Preferred Stock of Gen-Probe Incorporated. |
| 4.1(2) | Specimen common stock certificate. |
| 10.106 | Gen-Probe Employee Bonus Plan. |
| 10.107(6) | Form of Performance Stock Award Grant Notice and Performance Stock Award Agreement. |
| 10.108(7) | Amendment No. 2 to Credit Agreement dated as of February 11, 2010 by and between Gen-Probe Incorporated, as Borrower, and Bank of America, N.A., as Lender. |
| 31.1 | Certification dated May 5, 2010, of Principal Executive Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification dated May 5, 2010, of Principal Financial Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification dated May 5, 2010, of Principal Executive Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification dated May 5, 2010, of Principal Financial Officer required pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

Filed herewith.

Indicates
management
contract or
compensatory
plan, contract or
arrangement.

*

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

- (1) Incorporated by reference to Gen-Probe's Annual Report on Form 10-K filed with the SEC on February 25, 2010.
- (2) Incorporated by reference to Gen-Probe's Amendment No. 2 to Registration Statement on Form 10 (File No. 000-49834) filed with the SEC on August 14, 2002.
- (3) Incorporated by reference to Gen-Probe's Quarterly Report on Form 10-Q (File No. 001-31279) for the quarterly period ended June 30, 2004 filed with the SEC on August 9, 2004.
- (4) Incorporated by reference to Gen-Probe's Current Report on Form 8-K

filed with the
S E C o n
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 with respect to Items 5.02 and 9.01 filed with the SEC on February 16, 2010.
- (7) Incorporated by reference to Gen-Probe's Current Report on Form 8-K with respect to Items 1.01, 2.03 and 9.01 filed with the SEC on February 16, 2010.

Table of Contents

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 5, 2010

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

DATE: May 5, 2010

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