GEN PROBE INC
Form 10-Q
August 06, 2009

Table of Contents

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

(Mark One)

þ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended June 30, 2009

OR

o Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Commission File Number 001-31279

GEN-PROBE INCORPORATED
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**33-0044608**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
10210 Genetic Center Drive **San Diego, CA** (Address of Principal Executive Offices)	**92121** (Zip Code)

(858) 410-8000
(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant 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 o No o

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

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting Company o

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

As of July 31, 2009, there were 50,337,298 shares of the registrant s common stock, par value $0.0001 per share, outstanding.

GEN-PROBE INCORPORATED
TABLE OF CONTENTS
FORM 10-Q

Table of Contents

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

	June 30, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 233,506	$ 60,122
Marketable securities	230,698	371,276
Trade accounts receivable, net of allowance for doubtful accounts of $691 and $700 at June 30, 2009 and December 31, 2008, respectively	39,946	33,397
Accounts receivable other	2,852	2,900
Inventories	56,455	54,406
Deferred income tax	9,136	7,269
Prepaid income tax	6,863	2,306
Prepaid expenses	13,388	15,094
Other current assets	4,322	6,135
Total current assets	597,166	552,905
Marketable securities, net of current portion	105,037	73,780
Property, plant and equipment, net	153,767	141,922
Capitalized software, net	12,858	13,409
Goodwill	90,682	18,621
Deferred income tax, net of current portion	11,837	12,286
Purchased intangible assets, net	57,930	298
Licenses, manufacturing access fees and other assets, net	62,451	56,310
Total assets	$ 1,091,728	$ 869,531
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 19,477	$ 16,050
Accrued salaries and employee benefits	20,534	25,093
Other accrued expenses	10,983	4,027
Income tax payable	1,187	
Short-term borrowings	240,872	
Deferred income tax	1,406	
Deferred revenue	2,204	1,278
Total current liabilities	296,663	46,448
Non-current income tax payable	4,864	4,773
Deferred income tax, net of current portion	14,120	55
Deferred revenue, net of current portion	2,306	2,333
Other long-term liabilities	2,997	2,162
Commitments and contingencies		
Stockholders equity:		

Preferred stock, $0.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding		
Common stock, $0.0001 par value per share; 200,000,000 shares authorized, 50,581,177 and 52,920,971 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	5	5
Additional paid-in capital	292,828	382,544
Accumulated other comprehensive income	4,227	3,055
Retained earnings	473,718	428,156
Total stockholders equity	770,778	813,760
Total liabilities and stockholders equity	$ 1,091,728	$ 869,531

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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Product sales	$ 116,816	$ 113,701	$ 229,338	$ 215,208
Collaborative research revenue	2,187	4,651	3,862	7,110
Royalty and license revenue	1,542	1,462	3,528	20,059
Total revenues	120,545	119,814	236,728	242,377
Operating expenses:				
Cost of product sales (excluding acquisition-related intangibles amortization)	38,280	32,510	71,594	65,146
Acquisition-related intangibles amortization	1,114		1,114	
Research and development	26,069	29,368	51,067	52,434
Marketing and sales	14,015	11,453	25,070	23,361
General and administrative	17,823	13,671	31,670	25,608
Total operating expenses	97,301	87,002	180,515	166,549
Income from operations	23,244	32,812	56,213	75,828
Other income/(expense):				
Investment and interest income	10,122	3,900	15,004	8,107
Interest expense	(726)	(2)	(877)	(2)
Other income/(expense)	(895)	(191)	(1,037)	1,282
Total other income, net	8,501	3,707	13,090	9,387
Income before income tax	31,745	36,519	69,303	85,215
Income tax expense	11,930	11,728	23,741	28,479
Net income	$ 19,815	$ 24,791	$ 45,562	$ 56,736
Net income per share:				
Basic	$ 0.39	$ 0.46	$ 0.88	$ 1.05
Diluted	$ 0.38	$ 0.45	$ 0.87	$ 1.03
Weighted average shares outstanding:				
Basic	51,285	53,907	51,851	53,859
Diluted	52,061	55,147	52,598	55,093

See accompanying notes to consolidated financial statements.

Table of Contents

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

	Six Months Ended June 30,	
	2009	**2008**
Operating activities		
Net income	$ 45,562	$ 56,736
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	19,463	17,233
Amortization of premiums on investments, net of accretion of discounts	2,720	3,504
Stock-based compensation	11,405	9,228
Stock-based compensation income tax benefits	310	1,294
Excess tax benefit from stock-based compensation	(702)	(614)
Deferred revenue	(255)	(3,165)
Deferred income tax	(1,041)	(821)
Gain on sale of investment in MPI		(1,600)
Impairment of intangible assets		3,496
Loss / (gain) on disposal of property and equipment	69	(1)
Changes in assets and liabilities:		
Trade and other accounts receivable	1,372	3,290
Inventories	3,890	(2,749)
Prepaid expenses	3,137	5,333
Other current assets	2,081	(1,322)
Goodwill	856	
Other long-term assets	(2,486)	(909)
Accounts payable	(2,218)	3,992
Accrued salaries and employee benefits	(7,272)	(1,732)
Other accrued expenses	1,337	(9)
Income tax payable	(3,704)	(72)
Other long-term liabilities	335	603
Net cash provided by operating activities	74,859	91,715
Investing activities		
Proceeds from sales and maturities of marketable securities	293,504	205,283
Purchases of marketable securities	(189,091)	(318,558)
Purchases of property, plant and equipment	(14,666)	(25,717)
Capitalization of software development costs	(288)	
Purchases of intangible assets, including licenses and manufacturing access fees	(811)	(315)
Net cash paid for business combinations	(123,816)	
Proceeds from sale of investment in MPI		4,100
Cash paid for investment in DiagnoCure and related license fees	(5,250)	
Cash paid for Roche manufacturing access fees		(10,000)
Other assets	(289)	28
Net cash used in investing activities	(40,707)	(145,179)

Financing activities		
Excess tax benefit from stock-based compensation	702	614
Repurchase and retirement of restricted stock for payment of taxes	(38)	(479)
Repurchase and retirement of common stock	(105,577)	
Proceeds from issuance of common stock	3,777	10,814
Borrowings under short-term borrowings, net	238,450	
Net cash provided by financing activities	137,314	10,949
Effect of exchange rate changes on cash and cash equivalents	1,918	14
Net increase (decrease) in cash and cash equivalents	173,384	(42,501)
Cash and cash equivalents at the beginning of period	60,122	75,963
Cash and cash equivalents at the end of period	$ 233,506	$ 33,462

See accompanying notes to consolidated financial statements.

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 June 30, 2009, and for the three and six month periods ended June 30, 2009 and 2008, 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, 2009.

In accordance with Statement of Financial Accounting Standards (SFAS) No. 165, Subsequent Events, the Company has evaluated for material disclosure and recognition requirements all subsequent events from the balance sheet date of June 30, 2009 through August 6, 2009 and noted no such events.

Certain prior year amounts have been reclassified to conform to the current year presentation. In the quarter ended March 31, 2009, the Company began reporting investments in an unrealized loss position deemed to be temporary that have a contractual maturity of greater than 12 months as non-current marketable securities. This resulted in the reclassification of $73.8 million of marketable securities as non-current under the caption Marketable securities, net of current portion at December 31, 2008.

These unaudited consolidated financial statements and related footnotes should be read in conjunction with the audited consolidated financial statements and related footnotes contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2008.

Principles of consolidation

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

On April 8, 2009, the Company completed its acquisition of Tepnel Life Sciences plc (Tepnel), a United Kingdom (UK) based international life sciences products and services company. Tepnel s transplant diagnostics and genetic testing businesses are included in the Company s 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 June 30, 2009.

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; 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.

Foreign currencies

The Company translates the financial statements of its non-US 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.

Table of Contents

Fair value of financial instruments

The carrying value of cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities approximates fair value. See Note 5 for further discussion of fair value.

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.

The Company periodically reviews its available-for-sale 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 municipal securities with a current unrealized loss position to be other-than-temporarily impaired at June 30, 2009 since 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 June 30, 2009 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.

Revenue recognition

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

The Company manufactures blood screening products according to demand specifications of its collaboration partner, Novartis 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 its ultimate share of net sales by Novartis for these products, less the transfer price revenues previously recognized. The Company amended its 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.

Also included in product sales is the rental revenue associated with the delivery of the Company s proprietary integrated instrument platforms that perform its diagnostic assays. Generally, the Company provides its instrumentation to 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 Company 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.

Table of Contents

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 pharmaceutical, biotechnology, and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies and food testing kits.

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

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 the 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. Non-refundable license fees are recognized over the related performance period or at the time the Company has satisfied all performance obligations.

Adoption of recent accounting pronouncements

SFAS No. 165

In May 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 165, Subsequent Events. The statement does not require significant changes regarding recognition or disclosure of subsequent events, but does require disclosure of the date through which subsequent events have been evaluated for disclosure and recognition. The Company adopted this guidance effective June 30, 2009. Because this statement relates specifically to disclosure requirements, there was no impact on the Company s consolidated financial statements as a result of its adoption.

FSP SFAS No. 115-2

In April 2009, the FASB issued Staff Position (FSP) SFAS No. 115-2, Recognition and Presentation of Other-Than-Temporary Impairments, which became effective for interim and annual periods ending after June 15, 2009. FSP SFAS No. 115-2 modifies the guidance to determine whether the impairment of a debt security is other-than-temporary. This new standard also amends the presentation and disclosure requirements of

other-than-temporarily impaired debt and equity securities in the financial statements. The adoption of this statement did not have an effect on the Company s financial statements since any impairment on marketable securities is not considered to be other-than-temporary.

FSP SFAS No. 107-1

In April 2009, the FASB issued FSP SFAS No. 107-1 and Accounting Principles Board (APB) Opinion No. 28-1, Interim Disclosures about Fair Value of Financial Instruments, which the Company adopted on a prospective basis beginning April 1, 2009. This position extends the disclosure requirements of SFAS No. 107, Disclosures about Fair Value of Financial Instruments, to interim financial statements of publicly traded companies. Because this position relates specifically to disclosure requirements, there was no impact on our consolidated financial statements as a result of its adoption.

Table of Contents

EITF Issue No. 03-6-1

In June 2008, the FASB issued Staff Position EITF Issue No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities. EITF Issue No. 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the computation of earnings per share under the two-class method as described in SFAS No. 128, Earnings per Share. The Company adopted this guidance effective January 1, 2009. There was no material impact on the Company s consolidated financial statements as a result of the adoption of EITF Issue No. 03-6-1.

SFAS No. 161

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133. SFAS No. 161 requires enhanced disclosures regarding derivatives and hedging activities, including: (a) the manner in which an entity uses derivative instruments; (b) the manner in which derivative instruments and related hedged items are accounted for under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities; and (c) the effect of derivative instruments and related hedged items on an entity s financial position, financial performance, and cash flows. The Company adopted this guidance effective January 1, 2009. Because this statement relates specifically to disclosure requirements, there was no impact on the Company s consolidated financial statements as a result of its adoption.

SFAS No. 141(R)

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations. SFAS No. 141(R) changes the requirements for an acquirer s recognition and measurement of the assets acquired and liabilities assumed in a business combination, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, in-process research and development and restructuring costs. In addition, under SFAS No. 141(R), changes in an acquired entity s deferred tax assets and uncertain tax positions after the measurement period will impact income tax expense. The Company adopted this guidance effective January 1, 2009 and applied the accounting for business combinations to the Company s acquisition of Tepnel. See Note 2 for details on the impact of this statement on current and future operations, changes in estimates and unrecognized tax benefits and liabilities as a result of the Tepnel acquisition.

SFAS No. 160

In December 2007, the FASB issued SFAS No. 160, Non-controlling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin No. 51). SFAS No. 160 requires that non-controlling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the non-controlling interest be separately identified in the income statement, that changes in a parent s ownership interest while the parent retains its controlling interest be accounted for as equity transactions, and that any retained non-controlling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value. This statement is effective for fiscal years beginning after December 31, 2008, and must be applied prospectively. However, the presentation and disclosure requirements of SFAS No. 160 must be applied retrospectively for all periods presented. The retrospective presentation and disclosure requirements of this statement will be applied to any prior periods presented in financial statements for the fiscal year ending December 31, 2009 and later periods during which the Company has a consolidated subsidiary with a non-controlling interest. As of June 30, 2009, the Company does not have any consolidated subsidiaries in which it has a non-controlling interest, and therefore adoption of this statement did not have an impact on the Company s consolidated financial statements.

EITF Issue No. 07-1

In November 2007, the FASB ratified EITF Issue No. 07-1, Accounting for Collaborative Agreements Related to the Development and Commercialization of Intellectual Property. EITF Issue No. 07-1 defines collaborative agreements as a contractual arrangement in which the parties are active participants to the arrangement and are exposed to the significant risks and rewards that are dependent on the ultimate commercial success of the endeavor. Additionally, it requires that revenue generated and costs incurred on sales to third parties as it relates to a collaborative agreement be recognized as gross or net based on EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent. Essentially, this requires the party that is identified as the principal participant in a transaction to record the transaction on a gross basis in its financial statements. It also requires payments between

participants to be accounted for in accordance with already existing generally accepted accounting principles, unless none exist, in which case a reasonable, rational, consistent method should be used. The Company adopted this guidance effective January 1, 2009 for all collaboration agreements existing as of that date. There was no impact on the Company s consolidated financial statements as a result of the adoption of EITF Issue No. 07-1.

Table of Contents

Pending adoption of recent accounting pronouncements

SFAS No. 168

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162, which establishes the FASB Accounting Standards Codification (the Codification). The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental U.S. GAAP. All other accounting literature not included within the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009 and will be effective for interim and annual periods ending after September 15, 2009. Because this statement relates specifically to disclosure requirements, the Company does not expect any impact on its consolidated financial statements as a result of its adoption.

Note 2 Business combination

Acquisition of Tepnel Life Sciences plc

On April 8, 2009, the Company completed its acquisition of Tepnel, a UK-based international life sciences products and services company, which has two principal businesses, molecular diagnostics and research products and services. The acquisition was consummated pursuant to a court-sanctioned scheme of arrangement under Part 26 of the UK Companies Act 2006. 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 exchange rate of £1 to $1.48 as of the closing date. 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 exchange rate of £1 to $1.48 as of the closing date. 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).

In accordance with SFAS No. 141(R), the acquisition was accounted for as a business combination and, accordingly, the Company has included Tepnel s results of operations in its consolidated statements of income beginning in April 2009. Neither separate financial statements of Tepnel nor pro forma results of operations have been presented because the acquisition did not meet the quantitative materiality tests under Regulation S-X.

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

Table of Contents

Total purchase price	137,093
Exchange rate differences	(568)[1]
Allocated purchase price	$ 136,525
Net working capital	15,660
Fixed assets	11,352
Goodwill	70,997
Deferred tax liabilities	(15,599)
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
	$ 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 primary acquired intangible assets, including the customer relationships and trademarks and trade names, 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 customer relationships and will adjust, if necessary, the expected life, amortization method or carrying value of the customer relationships and trademarks and trade names, to best match the underlying economic value. The estimated amortization expense for these assets over future periods is as follows (in thousands):

Years ending December 31,	
Second half of 2009	$ 2,235
2010	4,470
2011	4,470

2012	4,470
2013	4,470
Thereafter	37,380
Total	$ 57,497

The $137.1 million purchase price exceeded the value of the acquired tangible and identifiable intangible assets, and therefore the Company has allocated $71.0 million to goodwill. Included in this goodwill amount is $15.6 million related to deferred tax liabilities recorded as a result of non-deductible amortization of acquired intangible assets. The Company believes the acquisition of Tepnel will provide access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerate the Company s ongoing strategic efforts to strengthen its marketing and sales, distribution and manufacturing capabilities in Europe.

Changes in goodwill for the six months ended June 30, 2009 were as follows (in thousands):

Goodwill balance as of December 31, 2008	$ 18,621
Additional goodwill recognized	70,997
Changes due to deferred tax assets/liabilities	90
Changes due to foreign translation	974
Goodwill balance as of June 30, 2009	$ 90,682

Table of Contents

At the date of acquisition, the Company assumed UK tax loss carryforwards estimated at $39.9 million. These losses do not expire, but the Company s ability to utilize these losses depends on its ability to generate future profits in the UK. The Company has established a $6.9 million valuation allowance against the full amount of deferred tax assets arising from these losses as the UK businesses of Tepnel have not yet turned profitable on a consistent basis. If UK profits are earned in future periods and the losses are utilized, any reduction in the valuation allowance will result in an income tax benefit being recorded in the Company s consolidated statements of income.

Approximately $3.2 million and $4.8 million of costs associated with the Company s acquisition of Tepnel have been included in general and administrative expenses for the three and six months ended June 30, 2009, respectively.

Note 3 Stock-based compensation

The following table summarizes the stock-based compensation expense that the Company recorded in its consolidated statements of income in accordance with SFAS No. 123(R), Share-Based Payment, for the three and six month periods ended June 30, 2009 and 2008 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	**2008**	**2009**	**2008**
Cost of product sales	$ 805	$ 592	$ 1,603	$ 1,187
Research and development	1,765	1,266	3,468	2,701
Marketing and sales	779	607	1,538	1,302
General and administrative	2,297	1,571	4,796	4,038
Total	$ 5,646	$ 4,036	$ 11,405	$ 9,228

Table of Contents

The Company used the following weighted average assumptions (annualized percentages) 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 and six month periods ended June 30, 2009 and 2008:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Stock Option Plans				
Risk-free interest rate	1.7%	2.6%	1.6%	2.7%
Volatility	36%	34%	36%	34%
Dividend yield				
Expected term (years)	4.2	4.2	4.2	4.2
Resulting average fair value	$ 13.50	$ 17.37	$ 13.30	$ 17.41
ESPP				
Risk-free interest rate	1.3%	3.3%	1.3%	3.3%
Volatility	47%	34%	47%	34%
Dividend yield				
Expected term (years)	0.5	0.5	0.5	0.5
Resulting average fair value	$ 12.20	$ 14.82	$ 12.20	$ 14.82

The Company s unrecognized stock-based compensation expense, before income taxes and adjusted for estimated forfeitures, related to outstanding unvested share-based payment awards as of June 30, 2009 was approximately as follows:

Awards	Weighted Average Remaining Expense Life (In years)	Unrecognized Expense as of June 30, 2009 (In thousands)
Options	1.2	$ 31,821
ESPP	0.2	187
Restricted Stock	1.7	10,429
Deferred Issuance Restricted Stock	1.6	2,439
		$ 44,876

Note 4 Net income per share

The Company computes net income per share in accordance with SFAS No. 128, Earnings Per Share, and SFAS No. 123(R). Basic net income per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing the net income for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options 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.

Table of Contents

The following table sets forth the computation of net income per share for the three and six month periods ended June 30, 2009 and 2008 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net income	$ 19,815	$ 24,791	$ 45,562	$ 56,736
Weighted average shares outstanding Basic	51,285	53,907	51,851	53,859
Effect of dilutive common stock options outstanding	776	1,240	747	1,234
Weighted average shares outstanding Diluted	52,061	55,147	52,598	55,093
Net income per share:				
Basic	$ 0.39	$ 0.46	$ 0.88	$ 1.05
Diluted	$ 0.38	$ 0.45	$ 0.87	$ 1.03

Dilutive securities include stock options and restricted stock subject to vesting. Potentially dilutive securities totaling approximately 3,541,000 and 1,882,000 shares for the three month periods ended June 30, 2009 and 2008, respectively, and 3,568,000 and 1,908,000 shares for the six month periods ended June 30, 2009 and 2008, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Note 5 Fair value measurements

SFAS No. 157

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

Level 1 Quoted prices for identical instruments in active markets.

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

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

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

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

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

The Company s available-for-sale securities are comprised of tax advantaged municipal securities and money market funds. When available, the Company generally uses quoted market prices to determine fair value, and classifies such items 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.

14

Table of Contents

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 June 30, 2009 (in thousands):

	Fair Value Measurements at June 30, 2009			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total carrying value in the consolidated balance sheet
Assets:				
Cash equivalents	$	$ 168,237	$	$ 168,237
Marketable securities		335,735		335,735
Other investments [(1)]		4,737		4,737
Total assets at fair value		508,709		508,709
Liabilities:				
Other investments [(1)]		4,936		4,936
Total liabilities at fair value	$	$ 4,936	$	$ 4,936

(1) Includes the Company s deferred compensation plan liability and related assets which are invested in corporate owned life insurance policies.

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

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

Equity investment in public company

In April 2009, the Company made a $5.0 million preferred stock investment in DiagnoCure, Inc. (DiagnoCure), a publicly held company traded on the Toronto Stock Exchange. The Company s equity investment was valued initially 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 June 30, 2009, is included in Licenses, manufacturing access fees and other assets, net on the Company s consolidated balance sheets.

Equity investment in private company

In 2006, the Company invested in Qualigen, Inc. (Qualigen), a private company. The valuation of investments in non-public companies requires significant management judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such assets. The Company s equity investments in private companies are valued initially based upon the transaction price under the cost method of accounting. Equity investments in non-public companies are classified as Level 3 in the fair value hierarchy. The Company s investment in Qualigen, which totaled approximately $5.4 million as of June 30, 2009, is included in Licenses, manufacturing access fees and other assets, net on the consolidated balance sheets.

The Company records impairment charges when an investment has experienced a decline that is deemed to be other-than-temporary. The determination that a decline is other-than-temporary is, in part, subjective and influenced by many factors. Future adverse changes in market conditions or poor operating results of investees could result in losses or an inability to recover the carrying value of the investments, thereby possibly requiring impairment charges in the future. When assessing investments in private companies for an other-than-temporary decline in value, the Company considers many factors, including, but not limited to, the following: the share price from the investee s latest financing round, the performance of the investee in relation to its own operating targets and its business plan, the investee s revenue and cost trends, the investee s liquidity and cash position, including its cash burn rate, and market acceptance of the investee s products and services. From time to time, the Company may consider third party evaluations or valuation reports. The Company also considers new products and/or services that the investee may have forthcoming, any significant news specific to the investee, the investee s competitors and/or industry and the outlook of the overall industry in which the investee operates. In the event the Company s judgments change as to other-than temporary declines in value, the Company may record an impairment loss, which could have an adverse effect on its results of operations. During the third quarter of 2008, the Company recorded an impairment charge of $1.6 million against its investment in Qualigen.

Table of Contents

SFAS No. 159

Effective January 1, 2008, the Company adopted SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115.

SFAS No. 159 provides companies the irrevocable option to measure many financial assets and liabilities at fair value with changes in fair value recognized in earnings. The Company has not elected to measure any financial assets or liabilities at fair value that were not previously required to be measured at fair value.

Note 6 Balance sheet information

The following tables provide details of selected balance sheet items as of June 30, 2009 and December 31, 2008 (in thousands):

Inventories

	June 30, 2009	December 31, 2008
Raw materials and supplies	$ 10,114	$ 8,529
Work in process	21,744	24,945
Finished goods	24,597	20,932
	$ 56,455	$ 54,406

Property, plant and equipment, net

	June 30, 2009	December 31, 2008
Land	$ 19,258	$ 18,804
Building	80,391	80,426
Machinery and equipment	174,364	153,211
Building improvements	42,241	34,592
Furniture and fixtures	17,241	16,270
Construction in-progress	558	19
Property, plant and equipment, at cost	334,053	303,322
Less accumulated depreciation and amortization	(180,286)	(161,400)
Property, plant and equipment, net	$ 153,767	$ 141,922

Purchased intangible assets, net

	June 30, 2009	December 31, 2008
Purchased intangible assets, at cost	$ 92,566	$ 33,636
Less accumulated amortization	(34,636)	(33,338)
Purchased intangible assets, net	$ 57,930	$ 298

Table of Contents

Licenses, manufacturing access fees and other assets, net

	June 30, 2009	December 31, 2008
Patents	$ 14,596	$ 13,962
Licenses and manufacturing access fees	59,595	64,507
Investment in Qualigen	5,404	5,404
Investment in DiagnoCure	5,000	
Other assets	6,097	3,611
Licenses and manufacturing access fees and other assets, at cost	90,692	87,484
Less accumulated amortization	(28,241)	(31,174)
Licenses and manufacturing access fees and other assets, net	$ 62,451	$ 56,310

Other accrued expenses

	June 30, 2009	December 31, 2008
Royalties	$ 3,181	$ 985
Professional fees	2,923	1,494
Warranty	821	923
Other	4,058	625
Other accrued expenses	$ 10,983	$ 4,027

Note 7 Marketable securities

The Company s available-for-sale securities include tax advantaged municipal securities with a minimum Moody s credit rating of A3 and a minimum Standard & Poor s credit rating of A-. As of June 30, 2009, the Company did not hold auction rate securities. The Company s investment policy limits the effective maturity on individual securities to six years and an average portfolio maturity to three years. At June 30, 2009, the Company s portfolios had an average term of three years and an average credit quality of AA2 as defined by Moody s.

The following is a summary of the Company s marketable securities as of June 30, 2009 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal securities	$ 334,114	$ 2,143	$ (522)	$ 335,735

The following table shows the estimated fair values and gross unrealized losses for the Company s investments in individual securities that have been in a continuous unrealized loss position deemed to be temporary for less than 12 months and for more than 12 months as of June 30, 2009 (in thousands):

	Less than 12 Months		More than 12 Months	
	Estimated	Unrealized Losses	Estimated	Unrealized Losses

	Fair Value		Fair Value	
Municipal securities	$ 92,149	$ (227)	$ 17,681	$ (295)

The unrealized losses on certain of the Company s investments in municipal securities were caused by interest rate increases. 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 June 30, 2009 since 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 June 30, 2009 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.

Table of Contents

The following table shows the current and non-current classification of the Company s marketable securities as of June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009	December 31, 2008
Current	$ 230,698	$ 371,276
Non-current	105,037	73,780
Total municipal securities	$ 335,735	$ 445,056

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 following table shows the gross realized gains and losses from the sale of marketable securities, based on the specific identification method, for the three and six month periods ended June 30, 2009 and 2008 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Proceeds from sale of marketable securities	$ 197,284	$ 14,862	$ 270,943	$ 29,267
Gross realized gains	$ 6,644	$ 89	$ 8,516	$ 407
Gross realized losses	(28)	(22)	(455)	(22)
Net realized gain	$ 6,616	$ 67	$ 8,061	$ 385

Note 8 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 March 2009, the Company borrowed $170.0 million under the revolving credit facility in anticipation of funding the Company s 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 and used approximately $137.1 million of such borrowings (based on the then applicable exchange rate) to fund the Company s acquisition of Tepnel. As of June 30, 2009, the total principal amount outstanding under the revolving credit facility was $240.0 million.

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.

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 June 30, 2009, the outstanding principal amount under this loan was £0.5 million, or $0.9 million based on the exchange rate of £1 to $1.65 as of the balance sheet date. The Company intends to pay off this debt within the next 12 months.

Table of Contents

Note 9 Income tax

As of June 30, 2009, the Company had total gross unrecognized tax benefits of $6.5 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 $4.9 million. Material filings subject to future examination are the Company s California returns filed for the 2005 through 2007 tax years, and the U.S. federal returns filed for the 2006 and 2007 tax years.

Note 10 Stockholders equity

Changes in stockholders equity for the six months ended June 30, 2009 were as follows (in thousands):

Balance at December 31, 2008	$ 813,760
Net income	45,562
Other comprehensive income, net	1,172
Proceeds from the issuance of common stock	1,700
Proceeds from the issuance of common stock through ESPP	2,077
Proceeds from the issuance of common stock to board members	90
Repurchase and retirement of common stock	(105,577)
Repurchase and retirement of restricted stock for payment of taxes	(38)
Stock-based compensation	11,330
Excess tax benefit from stock-based compensation	702
Balance at June 30, 2009	$ 770,778

Comprehensive income

In accordance with SFAS No. 130, Reporting Comprehensive Income, all components of comprehensive income, including net income, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, which includes certain changes in stockholders equity, such as foreign currency translation of the Company s wholly owned subsidiaries financial statements and unrealized gains and losses on available-for-sale securities, are reported, net of their related tax effect, to arrive at comprehensive income.

Components of comprehensive income, net of income tax, for the three and six month periods ended June 30, 2009 and 2008 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net income, as reported	$ 19,815	$ 24,791	$ 45,562	$ 56,736
Other comprehensive (loss) income:				
Foreign currency translation adjustment	3,419	9	3,359	84
Change in net unrealized gain on available-for-sale securities during the period	(311)	(2,758)	3,053	(1,275)
Reclassification adjustments:				
Net realized gains on available-for-sale securities	(4,300)	(44)	(5,240)	(250)
Total other comprehensive (loss) income, net	(1,192)	(2,793)	1,172	(1,441)

Comprehensive income	$ 18,623	$ 21,998	$ 46,734	$ 55,295

Table of Contents

Stock options

A summary of the Company s stock option activity during the six months ended June 30, 2009 for all equity incentive plans is as follows (in thousands, except price per share data and number of years):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	5,657	$ 44.12		
Granted	267	42.29		
Exercised	(85)	20.05		
Cancelled	(71)	54.22		
Outstanding at June 30, 2009	5,768	$ 44.26	4.6	$ 31,723
Exercisable at June 30, 2009	3,855	$ 38.91	4.1	$ 31,128

Restricted Stock

A summary of the Company s restricted stock activity during the six months ended June 30, 2009 for all equity incentive plans is as follows (in thousands, except price per share data):

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2008	294	$ 57.51
Granted	22	43.72
Vested and exercised	(10)	50.10
Forfeited	(6)	52.04
Unvested at June 30, 2009	300	$ 56.87

Stock Repurchase Program

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 years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the three months ended June 30, 2009, the Company repurchased and retired approximately 1,602,000 shares under this program at an average price of $43.66, or approximately $70.0 million in total. As of June 30, 2009, the Company has repurchased and retired approximately 4,182,000 shares since the program s inception at an average price of $43.17, or approximately $180.5 million in total. When stock is repurchased and retired, the amount paid in excess of par value is recorded to additional paid-in capital.

Note 11 Contingencies

The Company is a party to the following litigation and may be involved in other litigation in the ordinary course of business. The Company intends to vigorously defend its interests in these matters. The Company expects that the resolution of these matters will not have a material adverse effect on its business, financial condition or results of

operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

Digene Corporation

In December 2006, Digene Corporation (Digene) filed a demand for binding arbitration against F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. (together, Roche) with the International Centre for Dispute Resolution of the American Arbitration Association in New York (ICDR). 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.

Table of Contents

On April 1, 2009, a three-member arbitration panel from the ICDR issued an interim award rejecting all claims asserted by Digene in the arbitration proceeding brought by Digene against the Company and the Company s co-respondents Roche. The interim award remains subject to further proceedings related to its implementation, including requests by the Company and Roche for reimbursement of attorneys fees and related expenses.

Note 12 Derivative financial instruments

The Company enters 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 have a maturity of approximately 30 days and have not been designated as hedges in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activity. Accordingly, these instruments are marked to market at each balance sheet date with changes in fair value recognized in earnings under the caption other income/(expense).

The following table reflects the effect of these derivative instruments on the consolidated statements of income for the three and six month periods ended June 30, 2009 and 2008 (in thousands):

		Three Months Ended		Six Months Ended	
	Location of gain/(loss) recognized in	June 30,		June 30,	
Derivatives not designated as hedging instruments under SFAS No. 133:	**income**	**2009**	**2008**	**2009**	**2008**
Foreign currency forward contracts	Other income/(expense)	$ (807)	$	$ (635)	$

The Company did not have any foreign currency forward contracts outstanding at June 30, 2009.

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, includ the negative. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. We assume no obligation to update any forward-looking statements.

The following information should be read in conjunction with our June 30, 2009 consolidated 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, 2008 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, 2008. 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, 2008.

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for screening donated human blood. We also develop and manufacture nucleic acid probe-based products for the detection of harmful organisms in the environment and in industrial processes. We have over 25 years of research and development experience in nucleic acid detection, and our products, which are based on our patented nucleic acid testing, or NAT, technology, are used daily in clinical laboratories and blood collection centers throughout the world.

We have achieved strong growth in both revenues and earnings since we became a public company in 2002, primarily due to the success of our clinical diagnostic products for sexually transmitted diseases, or STDs, and blood screening products that are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, hepatitis C virus, or HCV, hepatitis B virus, or HBV, and West Nile Virus, or WNV. Under our collaboration agreement with Novartis Vaccines and Diagnostics, Inc., or Novartis, formerly known as Chiron Corporation, or Chiron, we manufacture blood screening products, while Novartis is responsible for marketing, sales and service of those products, which Novartis sells under its trademarks.

On April 8, 2009, we completed the acquisition of Tepnel Life Sciences plc (now Gen-Probe Life Sciences Ltd.) and its subsidiaries, or Tepnel, a UK-based international life sciences products and services company which has two principal businesses, molecular diagnostics and research products and services. We believe the acquisition of Tepnel will provide us access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe. The results of Tepnel s operations have been included in our consolidated financial statements beginning in April 2009.

Recent Events

Financial Results

Product sales for the second quarter of 2009 were $116.8 million, compared to $113.7 million in the same period of the prior year, an increase of 3%. Total revenues for the second quarter of 2009 were $120.5 million, compared to $119.8 million in the same period of the prior year, an increase of 1%. Net income for the second quarter of 2009 was $19.8 million ($0.38 per diluted share), compared to $24.8 million ($0.45 per diluted share) in the same period of the prior year, a decrease of 20%.

Product sales for the first six months of 2009 were $229.3 million, compared to $215.2 million in the same period of the prior year, an increase of 7%. Total revenues for the first six months of 2009 were $236.7 million, compared to $242.4 million in the same period of the prior year, a decrease of 2%. Net income for the first six months of 2009 was

$45.6 million ($0.87 per diluted share), compared to $56.7 million ($1.03 per diluted share) in the same period of the prior year, a decrease of 20%.

Table of Contents

Our total revenues, net income and fully diluted earnings per share in the first six months of 2009 included $8.2 million of one-time revenue associated with the renegotiation of our collaboration agreement with Novartis, as well as Tepnel s results of operations which were not included in the comparable prior year period. In contrast, the first six months of 2008 included $16.4 million of royalty and license revenue associated with the settlement payment received from Bayer (now Siemens Healthcare Diagnostics) which was recorded in the first quarter of 2008.

Acquisition of Tepnel Life Sciences plc

In April 2009, we completed our acquisition of Tepnel. The acquisition was consummated pursuant to a court-sanctioned scheme of arrangement under Part 26 of the UK Companies Act 2006. As a result of the acquisition, Tepnel became a wholly owned subsidiary of Gen-Probe Incorporated.

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 exchange rate of £1 to $1.48 as of the closing date. 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 exchange rate of £1 to $1.48 as of the closing date. The acquisition was financed through amounts borrowed under a senior secured revolving credit facility established with Bank of America, N.A., or Bank of America.`

Amended Collaboration Agreement with DiagnoCure Inc.

In April 2009, we and DiagnoCure, Inc., or DiagnoCure, entered into an amendment to the License, Development and Cooperation Agreement originally signed by the parties on November 19, 2003.

Pursuant to the amendment, we agreed to use our commercially reasonable efforts to obtain United States Food and Drug Administration, or FDA, approval of specified PCA3 assays and to file an application with the FDA for regulatory approval of a PCA3 assay in the United States by a specified date. In addition, we agreed to make annual payments of $0.5 million to DiagnoCure until specific milestones are met. After our cumulative net sales of licensed products exceed $50.0 million, half of the annual payments may be applied against future royalties due and payable to DiagnoCure under our agreement with DiagnoCure.

In addition, pursuant to the terms of the amendment, in April 2009 we paid $5.0 million to purchase 4.9 million shares of newly issued DiagnoCure preferred stock, which is convertible, in whole or in part at our election, into DiagnoCure common stock.

Credit Agreement

In February 2009, we entered into a credit agreement with Bank of America, which provided for a one-year senior secured revolving credit facility in an amount of up to $180.0 million that is subject to a borrowing base formula. The revolving credit facility has a sub-limit for the issuance of letters of credit in a face amount of up to $10.0 million. Advances under the revolving credit facility are intended to be used to consummate our acquisition of Tepnel and for other general corporate purposes. 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 connection with the credit agreement, we also entered into a security agreement, pursuant to which we secured our obligations under the credit agreement with a first priority security interest in the securities, cash and other investment property held in specified accounts maintained by Merrill Lynch, Pierce, Fenner & Smith Incorporated, an affiliate of Bank of America.

In March 2009, we borrowed $170.0 million under the revolving credit facility in anticipation of funding the acquisition of Tepnel. Also in March 2009, we amended the credit agreement with Bank of America to increase the amount that 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 with Bank of America and used approximately $137.1 million of such borrowings (based on the then applicable exchange rate) to fund our acquisition of Tepnel. As of June 30, 2009, the total principal amount outstanding under the revolving credit facility was $240.0 million.

In connection with the execution of the credit agreement with Bank of America, we terminated the commitments under our unsecured bank line of credit with Wells Fargo Bank, N.A., effective as of February 27, 2009. There were

no amounts outstanding under this line of credit as of the termination date.

Table of Contents

Corporate Collaboration with Novartis

In January 2009, we entered into an agreement, referred to herein as Amendment No. 11, with Novartis to amend the June 11, 1998 collaboration agreement, or the 1998 Agreement, between the parties. The effective date of Amendment No. 11 is January 1, 2009. Amendment No. 11 extends to June 30, 2025 the term of our blood screening collaboration with Novartis under the 1998 Agreement. The 1998 Agreement was scheduled to expire by its terms in 2013.

The 1998 Agreement provided that we were solely responsible for manufacturing costs incurred in connection with the collaboration, while Novartis was responsible for sales and marketing expenses associated with the collaboration. Amendment No. 11 provides that, effective January 1, 2009, we will recover 50% of our cost of product sales incurred in connection with the collaboration, which is recorded in the form of revenue. In addition, we will receive a percentage of the blood screening assay revenue generated under the collaboration, as described below.

The 1998 Agreement provided that we share revenue from the sale of blood screening assays under the collaboration with Novartis. Under the terms of the 1998 Agreement, as previously amended, our share of revenue from any assay that included a test for HCV was 45.75%. Amendment No. 11 modifies our share of such revenues, initially reducing it to 44% in 2009. Our share of blood screening assay revenue increases in subsequent years as follows: 2010-2011, 46%; 2012-2013, 47%; 2014, 48%; and 2015, 50%. Our share of blood screening assay revenue is fixed at 50% from January 1, 2015 though the remainder of the amended term of the agreement. Under Amendment No. 11, our share of blood screening assay revenue from any assay that does not test for HCV remains at 50%. Amendment No. 11 also provides that Novartis will reduce the amount of time between product sales and payment of our share of blood screening assay revenue from 45 days to 30 days. This reduction in reporting time allowed us to eliminate one month of the reporting lag for net revenues resulting in an $8.2 million one-time benefit in the first quarter of 2009.

As part of Amendment No. 11, Novartis has agreed to provide certain funding to customize our Panther instrument, a fully automated molecular testing platform now in development, for use in the blood screening market. Novartis has also agreed to pay us a milestone payment upon the first commercial sale of the Panther instrument. The parties will equally share any profit attributable to Novartis sale or lease of Panther instruments under the collaboration. The parties have also agreed to evaluate, using our technologies, the development of companion diagnostics for current or future Novartis medicines. Novartis has agreed to provide us with certain funding in support of initial research and development.

Stock Repurchase Program

In August 2008, our Board of Directors authorized the repurchase of up to $250.0 million of our common stock over the two years following adoption of the program, through negotiated or open market transactions. There is no minimum or maximum number of shares to be repurchased under the program. During the three months ended June 30, 2009, we repurchased and retired approximately 1,602,000 shares under this program at an average price of $43.66, or approximately $70.0 million in total. From its inception through June 30, 2009, we have repurchased and retired approximately 4,182,000 shares under this program at an average price of $43.17, or approximately $180.5 million in total.

Critical accounting policies and estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectability of accounts receivable, 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; 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 second quarter of 2009 to the items that we disclosed as our critical accounting policies and estimates in Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2008, except for the items discussed below.

Table of Contents

Marketable securities

The primary objectives of our 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. Our 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.

We periodically review our available-for-sale 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, we consider 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.

We do not consider our investments in municipal securities with a current unrealized loss position to be other-than-temporarily impaired at June 30, 2009 since we do not intend to sell the investments and it is not more likely than not that we 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 June 30, 2009 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 our current intent and ability to hold such investments to maturity.

Adoption of recent accounting pronouncements

EITF Issue No. 07-1

Effective January 1, 2009, we adopted Emerging Issues Task Force, or EITF, Issue No. 07-1, Accounting for Collaborative Agreements Related to the Development and Commercialization of Intellectual Property. EITF Issue No. 07-1 defines collaborative agreements as a contractual arrangement in which the parties are active participants to the arrangement and are exposed to the significant risks and rewards that are dependent on the ultimate commercial success of the endeavor. Additionally, it requires that revenue generated and costs incurred on sales to third parties as it relates to a collaborative agreement be recognized as gross or net based on EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent. Essentially, this requires the party that is identified as the principal participant in a transaction to record the transaction on a gross basis in its financial statements. It also requires payments between participants to be accounted for in accordance with already existing generally accepted accounting principles, unless none exist, in which case a reasonable, rational, consistent method should be used. The adoption of this statement did not have an impact on our consolidated financial statements, as all agreements were in compliance with this standard prior to its adoption.

SFAS No. 160

Effective January 1, 2009, we adopted Statement of Financial Accounting Standards, or SFAS, No. 160, Non-controlling Interests in Consolidated Financial Statements (an amendment of Accounting Research Bulletin No. 51). SFAS No. 160 requires that non-controlling (minority) interests be reported as a component of equity, that net income attributable to the parent and to the non-controlling interest be separately identified in the income statement, that changes in a parent s ownership interest while the parent retains its controlling interest be accounted for as equity transactions, and that any retained non-controlling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value. As of June 30, 2009, we did not have any consolidated subsidiaries in which we had a non-controlling interest, and therefore adoption of this statement did not have an impact on our consolidated financial statements.

SFAS No. 141(R)

Effective January 1, 2009, we adopted SFAS No. 141(R), Business Combinations. SFAS No. 141(R) changes the requirements for an acquirer s recognition and measurement of the assets acquired and liabilities assumed in a business combination, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, in-process research and development and restructuring costs. In addition, under SFAS No. 141(R), changes in an

acquired entity s deferred tax assets and uncertain tax positions after the measurement period will impact income tax expense. See Note 2 Business combination, of the Notes to the Consolidated Financial Statements included in Item 1 of Part I of this report for the impact of the adoption of SFAS No. 141(R) on our financial results as of June 30, 2009.

Table of Contents

SFAS No. 161

Effective January 1, 2009, we adopted SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133. SFAS No. 161 requires enhanced disclosures regarding derivatives and hedging activities, including: (a) the manner in which an entity uses derivative instruments; (b) the manner in which derivative instruments and related hedged items are accounted for under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities; and (c) the effect of derivative instruments and related hedged items on an entity s financial position, financial performance, and cash flows. Because this statement relates specifically to disclosure requirements, there was no impact on our consolidated financial statements as a result of its adoption.

EITF Issue No. 03-6-1

Effective January 1, 2009, we adopted Financial Accounting Standards Board, or FASB, Staff Position EITF Issue No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities. EITF Issue No. 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the computation of earnings per share under the two-class method as described in SFAS No. 128, Earnings per Share. There was no material impact on our consolidated financial statements as a result of the adoption of EITF Issue No. 03-6-1.

FSP SFAS No. 115-2

Effective April 1, 2009, we adopted FASB Staff Position, or FSP, SFAS No. 115-2, Recognition and Presentation of Other-Than-Temporary Impairments. FSP SFAS No. 115-2 modifies the guidance to determine whether the impairment of a debt security is other-than-temporary. This new standard also amends the presentation and disclosure requirements of other-than-temporarily impaired debt and equity securities in the financial statements. The adoption of this statement did not have an effect on our consolidated financial statements since any impairment on marketable securities is not considered to be other-than-temporary.

FSP SFAS No. 107-1

Effective April 1, 2009, we adopted FSP SFAS No. 107-1 and Accounting Principles Board, or APB, Opinion No. 28-1, Interim Disclosures about Fair Value of Financial Instruments. FSP SFAS No. 107-1 extends the disclosure requirements of SFAS No. 107, Disclosures about Fair Value of Financial Instruments, to interim financial statements of publicly traded companies. Because this position relates specifically to disclosure requirements, there was no impact on our consolidated financial statements as a result of its adoption.

SFAS No. 165

Effective June 30, 2009, we adopted SFAS No. 165, Subsequent Events. The standard does not require significant changes regarding recognition or disclosure of subsequent events, but does require disclosure of the date through which subsequent events have been evaluated for disclosure and recognition. Because this statement relates specifically to disclosure requirements, there was no impact on our consolidated financial statements as a result of its adoption.

Pending adoption of recent accounting pronouncements

SFAS No. 168

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162, which establishes the FASB Accounting Standards Codification, or the Codification. The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental U.S. GAAP. All other accounting literature not included in the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009 and will be effective for interim and annual periods ending after September 15, 2009. Because this statement relates specifically to disclosure requirements, we do not expect any impact on our consolidated financial statements as a result of its adoption.

Table of Contents

Results of Operations

Product Sales

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Clinical diagnostics	$ 67.8	$ 57.2	$ 10.6	19%	$ 127.4	$ 109.7	$ 17.7	16%
Blood screening	45.8	56.5	(10.7)	(19)%	98.7	105.5	(6.8)	(6)%
Research products and services	3.2		3.2	N/M	3.2		3.2	N/M
Product Sales	**$ 116.8**	**$ 113.7**	**$ 3.1**	**3%**	**$ 229.3**	**$ 215.2**	**$ 14.1**	**7%**
As a percent of total revenues	97%	95%			97%	89%		

Our primary source of revenue comes from product sales, which consist primarily of the sale of clinical diagnostic and blood screening products in the United States and throughout the world. Our clinical diagnostic product sales consist primarily of our APTIMA, PACE, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines, as well as sales of transplant diagnostics and genetic testing products acquired as part of our recent acquisition of Tepnel, which are primarily sold under the LIFEMATCH and Elucigene trademarks. 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 by 3% and 7% in the three and six months ended June 30, 2009, respectively, as compared to the same periods of 2008. In each case, the increase was primarily attributed to additional product sales as a result of our recent acquisition of Tepnel and higher APTIMA assay sales, partially offset by lower blood screening sales, primarily due to lower shipments and unfavorable exchange rate impacts.

Diagnostic product sales

The increase in diagnostic product sales in the three and six months ended June 30, 2009 compared to the same periods of the prior year is primarily attributed to the addition of transplant diagnostic and genetic testing product sales resulting from our acquisition of Tepnel, volume gains in our APTIMA product line as the result of PACE conversions, market share gains we attribute to the superior clinical performance of our APTIMA assays, and the availability of our fully automated TIGRIS instrument.

In general, the price of our amplified APTIMA test is twice that of our non-amplified PACE product, thus the conversion from PACE to APTIMA drives an overall increase in product sales even if underlying testing volumes remain the same.

During the three and six months ended June 30, 2009, diagnostic product sales were negatively affected by unfavorable estimated exchange rate impacts of $1.2 million and $2.7 million, respectively, due to a stronger United States dollar.

Table of Contents

Blood screening related sales

The decrease in blood screening related sales in the three and six months ended June 30, 2009 compared to the same periods of the prior year is primarily attributed to test demand fluctuations from our partner Novartis. Second quarter 2008 blood screening test demand and the related shipment of tests was $8.8 million higher than the second quarter of 2009, primarily associated with higher WNV test demand and the additional tests required for the Ultrio post-marketing yield study which concluded at the end of 2008, as well as lower shipments of the Procleix Ultrio HIV-1/HCV assay in the six months ended June 30, 2009 as customers prepare to adopt the Procleix Ultrio assay. In addition, in the prior year period we recorded $2.6 million related to historical revenue adjustments as a result of our amended collaboration agreement with Novartis.

During the three and six months ended June 30, 2009, blood screening related product sales were negatively affected by unfavorable estimated exchange rate impacts of $3.1 million and $5.8 million, respectively, due to a stronger United States dollar.

Research Products and Services

As a result of our acquisition of Tepnel, we have a new category of product sales, which we refer to as Research products and services. These sales represent outsourcing services for pharmaceutical, biotechnology, and healthcare industries, including nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies and food testing kits. These sales totaled $3.2 million for the three and six months ended June 30, 2009.

Collaborative research revenue

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Collaborative Research Revenue	$ 2.2	$ 4.6	$ (2.4)	(52)%	$ 3.9	$ 7.1	$ (3.2)	(45)%
As a percent of total revenues	2%	4%			2%	3%		

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

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

Collaborative research revenue decreased 52% and 45% in the three and six months ended June 30, 2009, respectively, as compared to the same periods of 2008. In each case, the decrease was primarily due to $2.7 million of previously deferred milestone revenue received in the prior year period from 3M Corporation, or 3M, related to our healthcare-associated infection collaboration which ended in June 2008, partially offset by increased reimbursements from Novartis for shared development expenses, primarily attributable to development efforts for the Panther instrument.

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

Royalty and license revenue

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Royalty and License Revenue	$ 1.5	$ 1.5	$	0%	$ 3.5	$ 20.1	$ (16.6)	(83)%
As a percent of total revenues	1%	1%			1%	8%		

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 in the second quarter of 2009 was unchanged compared to the second quarter of 2008.

Royalty and license revenue decreased 83% in the first six months of 2009 compared to the same period of the prior year. The $16.6 million decrease was primarily due to the $16.4 million settlement payment received from Bayer during the first quarter of 2008. Bayer has now paid all amounts due to us under our settlement agreement.

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

Cost of product sales

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Cost of Product Sales	$ 38.3	$ 32.5	$ 5.8	18%	$ 71.6	$ 65.1	$ 6.5	10%
Gross profit margin as a percent of product sales	67%	71%			69%	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 outside the United States is capitalized to inventory and classified as cost of product sales upon shipment.

Our blood screening manufacturing facility has operated, and we expect that it will continue to operate for the foreseeable future, below its potential capacity. A portion of this available capacity is utilized for R&D activities as

new product offerings are developed for commercialization. As a result, certain operating costs of our blood screening manufacturing facility, together with other manufacturing costs for the production of pre-commercial development lot assays that are delivered under the terms of an Investigational New Drug, or IND, application are classified as R&D expense prior to FDA approval.

Cost of sales increased 18% in the second quarter of 2009 compared to the second quarter of 2008. The $5.8 million increase was primarily due to an additional $4.4 million in cost of product sales as a result of our recent acquisition of Tepnel and an increase of $3.0 million attributed to manufacturing variances related to changes in production volumes, partially offset by a decrease of $2.9 million attributed to lower blood screening shipment volume.

Cost of sales increased 10% in the six months ended June 30, 2009, compared to the same period of the prior year. The $6.5 million increase was primarily due to an additional $4.4 million in cost of product sales as a result of our recent acquisition of Tepnel, an increase of $4.7 million attributed to manufacturing variances related to changes in production volumes and an increase of $1.7 million related to increased APTIMA sales, partially offset by a decrease of $3.5 million attributed to lower blood screening shipment volume and a decrease of $3.5 million related to lower instrument sales and instrument related costs.

Table of Contents

Our gross profit margin as a percentage of product sales decreased to 67% and 69% in the three and six months ended June 30, 2009, respectively, from 71% and 70% during the same periods of 2008. The decreases in gross profit margin percentages were principally attributed to the following:

lower overall gross margin percentages for the recently acquired Tepnel business;

an increase in cost of sales related to changes in production volumes; and

an increase in the amortization of intellectual property associated with the commercialization of our CE-marked APTIMA HPV assay; partially offset by

an increase in instrumentation margins.

Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales 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 $4.8 million and $6.9 million during the first six months of 2009 and 2008, respectively. Under our collaboration agreement with Novartis, we sell TIGRIS instruments to them at prices that approximate cost and share in profits of end-user sales in the United States. These instrument sales, therefore, negatively impact our gross margin percentage in the periods when they occur, but are a necessary precursor to increased sales of blood screening assays in the future.

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 used. The greater number of tests required for smaller pool sizes will increase our variable manufacturing costs, including costs of raw materials and labor. In 2008, we were responsible for 100% of the cost of product sales pursuant to our collaboration agreement with Novartis. Effective January 1, 2009, our amended collaboration agreement with Novartis provides that we will recover 50% of our cost of product sales incurred in connection with the collaboration, which is recorded in the form of revenue. 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 by a customer of smaller pool sizes. We have already observed this trend with respect to certain sales internationally. We are not able to predict accurately the ultimate extent to which our gross profit margin percentage will be negatively affected as a result of smaller pool sizes, because we do not know the ultimate selling price that Novartis will charge to the end user or the degree to which smaller pool size testing will be adopted across the markets in which we sell our products.

Acquisition-related intangibles amortization

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Acquisition-related intangibles amortization	$ 1.1	$	$ 1.1	N/M	$ 1.1	$	$ 1.1	N/M
As a percent of total revenues	1%	0%			0%	0%		

Amortization expense related to purchased intangible assets was $1.1 million during the three and six months ended June 30, 2009 as a result of our acquisition of Tepnel. 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 acquisition of Tepnel, please refer to Note 2 Business combination, of the Notes to the Consolidated Financial Statements included in Item 1 of Part I of this report.

Research and development

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Research and Development	$ 26.1	$ 29.4	$ (3.3)	(11)%	$ 51.1	$ 52.4	$ (1.3)	(2)%
As a percent of total revenues	22%	25%			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.

Table of Contents

We expect to incur additional costs associated with our research and development activities. The additional costs include the development and validation activities for our PCA3 and HPV assays, development of our Panther instrument, our fully automated system for low and mid-volume laboratories, 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 decreased 11% in the second quarter of 2009 compared to the second quarter of 2008. The $3.3 million decrease was primarily due to a $3.5 million impairment charge recorded in the second quarter of 2008 associated with our Corixa license agreement.

R&D expenses decreased 3% in the six months ended June 30, 2009 compared to the same period of the prior year. The $1.4 million decrease was primarily due to a $3.5 million impairment charge recorded in the second quarter of 2008 associated with our Corixa license agreement, partially offset by increased spending for clinical evaluations and outside services associated with our HPV clinical trial.

Marketing and sales

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Marketing and Sales	$ 14.0	$ 11.4	$ 2.6	23%	$ 25.1	$ 23.4	$ 1.7	7%
As a percent of total revenues	12%	10%			11%	10%		

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

Marketing and sales expenses increased 23% and 7% in the three and six months ended June 30, 2009, respectively, compared to the same periods of the prior year. These increases are primarily attributed to the addition of $1.8 million in marketing and sales expenses as a result of our recent acquisition of Tepnel, continued investment in global expansion efforts, primarily in Western Europe, and the related promotion and sale of our CE-marked PCA3 and HPV products.

General and administrative

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
General and Administrative	$ 17.8	$ 13.7	$ 4.1	30%	$ 31.7	$ 25.6	$ 6.1	24%
As a percent of total revenues	15%	11%			13%	11%		

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

G&A expenses increased 30% and 24% in the three and six months ended June 30, 2009, respectively, compared to the same periods of the prior year. These increases are primarily attributed to the addition of Tepnel s G&A expenses which totaled $2.7 million in both the three and six months ended June 30, 2009, as well as business development costs associated with the acquisition, which totaled $3.2 million and $4.8 million in the three and six months ended June 30, 2009, respectively.

Total other income, net

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	**2008**	**$ Change**	**% Change**	**2009**	**2008**	**$ Change**	**% Change**
Investment and interest income	$ 10.1	$ 3.9	$ 6.2	159%	$ 15.0	$ 8.1	$ 6.9	85%
Interest expense	(0.7)		(0.7)	N/M	(0.9)		(0.9)	N/M
Other income / (expense)	(0.9)	(0.2)	(0.7)	N/M	(1.0)	1.3	(2.3)	N/M
Total other income, net	**$ 8.5**	**$ 3.7**	**$ 4.8**	129%	**$ 13.1**	**$ 9.4**	**$ 3.7**	39%

The above increases in investment and interest income and interest expense are primarily attributable to realized gains on the sale of marketable securities and the borrowings under our credit facility with Bank of America, respectively. The net increase in other expense was primarily attributable to a $1.6 million gain recorded in the first quarter of 2008 resulting from the sale of our equity interest in Molecular Profiling Institute, Inc., offset by unfavorable exchange rate impacts.

Table of Contents

Income tax expense

(Dollars in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	$ Change	% Change	2009	2008	$ Change	% Change
Income Tax Expense	$ 11.9	$ 11.7	$ 0.2	2%	$ 23.7	$ 28.5	$ (4.8)	(17)%
As a percent of income before tax	37%	32%			34%	33%		

The increase in our effective tax rate for the three and six months ended June 30, 2009 compared to the same periods of the prior year were primarily due to the following:

non-deductible transaction fees related to our acquisition of Tepnel;

a decrease in our anticipated tax advantaged interest income for the year; and

benefits recognized in the prior year upon settlement of an IRS audit.

We estimate that our annual effective tax rate for 2009 will be approximately 33% to 35%, compared to the prior year effective tax rate of approximately 34%.

Liquidity and capital resources

	June 30, 2009	December 31, 2008
	(In thousands)	
Cash, cash equivalents and current marketable securities	$ 464,204	$ 431,398
Working capital	300,503	506,457
Current ratio	2.0	11.9

Our working capital at June 30, 2009 decreased $206.0 million from December 31, 2008 primarily due to the current liability created by our credit facility with Bank of America, which was partially offset by the subsequent drawdown on that credit facility as an increase to cash. In April 2009, we used approximately $137.1 million in borrowings under the credit facility to acquire Tepnel. Also contributing to the decrease in working capital was an increase in investments in an unrealized loss position deemed to be temporary at June 30, 2009 that have a contractual maturity of greater than 12 months, which have been classified as non-current marketable securities.

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 available-for-sale securities include tax advantaged municipal securities with a minimum Moody s credit rating of A3 and a minimum Standard & Poor s credit rating of A-. As of June 30, 2009, 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 June 30, 2009, our portfolios had an average term of three years and an average credit quality of AA2 as defined by Moody s.

	Six Months Ended June 30,		
	2009	2008	$ Change
	(In thousands)		
Cash provided by (used in):			
Operating activities	$ 74,859	$ 91,715	$ (16,856)
Investing activities	(40,707)	(145,179)	104,472

Financing activities	137,314	10,949	126,365
Purchases of property, plant and equipment (included in investing activities above)	(14,666)	(25,717)	(11,051)

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 the first six months of 2009 by our recently established credit facility with Bank of America, described above under Recent Events. 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 to continue the repurchase of our common stock under our stock repurchase program, as well as 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.

Table of Contents

Operating activities provided net cash of $74.9 million for the first six months of 2009, primarily from net income of $45.6 million, net non-cash charges of $28.3 million and an increase in cash from operating assets and liabilities of $1.0 million. Non-cash charges primarily consisted of depreciation of $14.1 million, amortization of intangibles of $5.4 million and stock based compensation expense of $11.4 million.

Net cash used in investing activities for the first six months of 2009 was $40.7 million. Net cash paid for the acquisition of Tepnel totaled $123.8 million, $14.7 million was used for purchases of property, plant and equipment, and $5.0 million was used to purchase preferred stock in DiagnoCure. These uses of cash were offset by $104.4 million in net proceeds from the sale of marketable securities.

Net cash provided by financing activities for the first six months of 2009 was $137.3 million, primarily driven by $240.0 million in borrowings under our credit facility, partially offset by $105.6 million used to repurchase and retire approximately 2,477,000 shares of our common stock under our stock repurchase program.

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

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

Contractual obligations and commercial commitments

Our contractual obligations due as of June 30, 2009 were as follows (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Material purchase commitments [1]	$ 36,442	$ 19,014	$ 17,428	$	$
Operating leases [2]	5,313	1,037	2,031	1,614	631
Collaborative commitments [3]	5,782	200	3,458	750	1,374
Minimum royalty commitments [4]	9,505	960	3,545	3,090	1,910
Deferred employee compensation [5]	3,291	951	1,108	833	399
Capital leases [6]	943	451	423	69	
Total[7]	$ 61,276	$ 22,613	$ 27,993	$ 6,356	$ 4,314

(1) Amounts represent our minimum purchase commitments from key vendors for the TIGRIS, Panther and Luminex instruments, as well as raw

materials used in manufacturing. Of the $36.4 million total, $25.9 million is expected to be used to purchase TIGRIS instruments, of which we anticipate that approximately $15.4 million of instruments will be sold to Novartis. Not included in the $36.4 million is $6.6 million expected to be used to purchase pre-production and production instruments, and associated tooling, pursuant to our development agreement with Stratec Biomedical Systems AG, or Stratec, for the Panther instrument, as well as potential minimum purchase commitments under our supply agreement with Stratec. Our obligations under the supply agreement are contingent on successful completion of all activities

under the development agreement with Stratec.

(2) Reflects obligations for facilities and vehicles under operating leases in place as of June 30, 2009. Future minimum lease payments are included in the table above.

Table of Contents

(3) In addition to the minimum payments due under our collaborative agreements, we may be required to pay up to $12.2 million in milestone payments, plus royalties on net sales of any products using specified technology. We may also be required to pay up to $5.2 million in future development costs in the form of milestone payments.

(4) Amounts represent our minimum royalties due on the net sales of products incorporating licensed technology and subject to a minimum annual royalty payment. During the three and six months ended June 30, 2009, we recorded $2.2 million and $3.8 million, respectively, in royalty costs related to our

various license agreements.

(5) We have liabilities for deferred employee compensation which totaled $4.9 million at June 30, 2009. These liabilities are typically dependent upon when certain key employees retire or otherwise leave the Company. Of the $4.9 million, $1.6 million was not included in the table above as we cannot reasonably predict when these events may occur. Total liabilities for deferred employee compensation are partially offset by deferred compensation assets, which totaled $4.7 million at June 30, 2009.

(6) Reflects obligations on capital leases in place as of June 30, 2009. Interest amounts were not material, therefore,

capital lease obligations were shown net of interest expense in the table above.

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

Liabilities associated with uncertain tax positions, currently estimated at $6.5 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.

As of June 30, 2009, 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 2010. For additional information regarding the terms of this credit facility, please see the description included under Recent Events above.

We do not currently have and have never had any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been

established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Available Information

Copies of our public filings are available on our Internet website at http://www.gen-probe.com as soon as reasonably practicable after we electronically file such material with, or furnish them to, the 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 one-year senior secured revolving credit facility with Bank of America. As of June 30, 2009, 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 $7.3 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 United States dollars, some portions of our revenue are realized in foreign currencies. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. We translate the financial statements of our non-US 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 six months of 2009, a 10% movement of currency exchange rates would result in a blood screening product sales increase or decrease of approximately $5.9 million annually. Similarly, a 10% movement of currency exchange rates would result in a diagnostic product sales increase or decrease of approximately $2.5 million annually. Our exposure for both blood screening and diagnostic product sales is primarily in the United States dollar versus the Euro, British pound, Australian dollar, and Canadian dollar.

Our total payables denominated in foreign currencies as of June 30, 2009 were not material. Our receivables by currency as of June 30, 2009 reflected in U.S. dollar equivalents were as follows (in thousands):

British pounds	$ 3,271
Canadian dollars	1,691
Danish kroner	18
Euros	4,056
U.S. dollars	31,600
Total gross trade accounts receivable	$ 40,636

In order to reduce the effect of foreign currency fluctuations, we utilize foreign currency forward exchange 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. Although the effect of currency fluctuations on our financial results has generally been immaterial in the past, we recorded a realized loss of $0.9 million in the second quarter of 2009.

We did not have any foreign currency forward contracts outstanding at June 30, 2009.

Item 4. Controls and Procedures

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

reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Table of Contents

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 June 30, 2009.

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

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As of the date of the foregoing evaluation, we have not completed our assessment of Tepnel s internal control over financial reporting, which remains ongoing. As a result, we have excluded Tepnel from the evaluation of our internal control over financial reporting contained in this report.

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 11 Contingencies, of the Notes to the Consolidated Financial Statements included in Item 1 of Part I of this report and is incorporated by reference herein. We are also engaged from time to time in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. If any of these matters were resolved in a manner unfavorable to us, our business, financial condition and results of operations would be harmed.

Item 1A. Risk Factors

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 facing us. Other events that we do not currently anticipate or that we currently deem immaterial also may 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, 2008. In addition, we have added a risk factor relating to our revolving credit facility.

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, changes and fluctuations in demand for blood screening tests from our collaboration partner Novartis, the timing of acquisitions, the execution of customer contracts, or the receipt of milestone payments, or the failure to achieve and receive the same, and the initiation or termination of corporate collaboration agreements. For example, commencing in April 2009, our consolidated financial results include the results of operations of Tepnel. In addition, a significant portion of our costs also can vary substantially between quarterly or annual reporting periods. For example, the total amount of research and development costs in a period often depends on the amount of costs we incur in connection with manufacturing developmental lots and clinical trial lots. Moreover, a variety of factors may affect our ability to make accurate forecasts regarding our operating results. For example, certain of our blood screening products, oncology and industrial products, as well as some of our clinical diagnostic products, have a relatively limited sales history, which limits our ability to project future sales, prices and the sales cycles accurately. In addition, we base our internal projections of blood screening product sales and international sales of various diagnostic products on projections prepared by our distributors of these products and therefore we are dependent upon the accuracy of those projections. We expect continuing fluctuations in our manufacture and shipment of blood screening products to Novartis, which vary each period based on Novartis inventory levels and supply chain needs. Because of all of these factors, our operating results in one or more future quarters may fail to meet or exceed financial guidance we may provide from time to time and the expectations of securities analysts or investors, which could cause our stock price to decline. In addition, the trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about our business and that of our competitors. Furthermore, failure to achieve our operational goals may inhibit our targeted growth plans and the successful implementation of our strategic objectives.

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 economy, or a reduction in customer spending or

credit availability, could result in downward pricing pressures, delayed or decreased purchases of our products and longer sales cycles. Furthermore, during challenging economic times our customers may face issues gaining timely access to sufficient credit, which could result in an impairment of their ability to make timely payments to us. If that were to occur, we may be required to increase our allowance for doubtful accounts. If economic and market conditions in the United States or other key markets persist, spread, or deteriorate further, we may experience adverse effects on our business, operating results and financial condition.

Table of Contents

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 42% of our total revenues during the first six months of 2009 and 44% of total revenues for 2008. As described above, Amendment No. 11 extends to June 30, 2025 the term of our blood screening collaboration with Novartis under the 1998 Agreement. The 1998 Agreement was previously scheduled to expire by its terms in 2013. The collaboration agreement can be terminated by either party prior to the expiration of its term if the other party materially breaches the collaboration agreement and does not cure the breach following 90 days notice, or if the other party becomes insolvent or declares bankruptcy.

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

Our agreement with Siemens, as assignee of Bayer, for the distribution of certain of our products will terminate in 2010. In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. In August 2006, we entered into a settlement agreement with Bayer regarding this arbitration and the patent litigation between the parties. Under the terms of the settlement agreement, the parties submitted a stipulated final award adopting the arbitrator s prior interim and supplemental awards, except that Bayer was no longer obligated to reimburse us $2.0 million for legal expenses previously awarded in the arbitrator s June 5, 2005 interim award. The arbitrator determined that the collaboration agreement should be terminated, as we requested, except as to the qualitative HCV assays and as to quantitative Analyte Specific Reagents, or ASRs, for HCV. As Bayer s assignee, Siemens retains the co-exclusive right to distribute the qualitative HCV tests and the exclusive right to distribute the quantitative HCV ASR. As a result of the termination of the collaboration agreement, we re-acquired the right to develop and market future viral assays that had been previously reserved for Siemens. The arbitrator s March 3, 2006 supplemental award determined that we are not obligated to pay an initial license fee in connection with the sale of the qualitative HIV-1 and HCV assays and that we will be required to pay running sales royalties, at rates we believe are generally consistent with rates paid by other licensees of the relevant patents.

We rely upon bioMérieux for distribution of certain of our products in most of Europe and Australia, 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 agreement with Fujirebio terminates in December 2010, although it may terminate earlier under certain circumstances. Our distribution agreement with bioMérieux terminates in May 2012, although it may terminate earlier under certain circumstances.

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

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

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

Table of Contents

In November 2007, for example, 3M informed us that it no longer intended to fund our collaboration to develop rapid molecular assays for the food testing industry. We and 3M subsequently terminated this agreement. In June 2008, 3M discontinued our collaboration to develop assays for healthcare-associated infections. While we are currently seeking other opportunities to commercialize our prototype assays in these fields, there is no guarantee we will be successful in these efforts.

The continuation of any of our collaboration agreements depends on their periodic renewal by us and our collaborators. For example, we recently entered into Amendment No. 11 with Novartis which extends to June 30, 2025 the term of our blood screening collaboration with Novartis under the 1998 Agreement. The 1998 Agreement was previously scheduled to expire by its terms in 2013. The collaboration agreement can be terminated by either party prior to the expiration of its term if the other party materially breaches the collaboration agreement and does not cure the breach following 90 days notice, or if the other party becomes insolvent or declares bankruptcy.

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 with respect to acquiring other companies. Any future acquisitions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all. For example, in July 2008 we withdrew our counterbid to acquire Innogenetics NV as a result of a higher offer made by Solvay Pharmaceuticals. Prior to withdrawing our bid, our management devoted substantial time and attention to the proposed transaction. Further, we nonetheless incurred related transaction costs, including legal, accounting and other fees.

On April 8, 2009, we completed the acquisition of Tepnel for approximately $137.1 million (based on the then applicable GBP to USD exchange rate). We believe the Tepnel acquisition will provide us access to growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerate our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe. These expectations 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 acquisition of Tepnel and 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 an acquisition;
- the inability to retain or replace key employees of any acquired businesses or hire enough qualified personnel to staff any new or expanded operations;
- the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;

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

the exposure to unknown liabilities;

Table of Contents

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

increased amortization expenses if an acquisition includes significant intangible assets;

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

the risk of entering new markets; and

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

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

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 impact 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. Since August 2008, existing customers have not transitioned from the use of the Procleix HIV-1/HCV blood screening assay to the use of the Procleix Ultrio assay at the levels we anticipated. We believe this is attributable in part to the FDA s current requirements for testing blood donations, which do not currently mandate testing for HBV 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 utility of NAT testing

for HBV, no formal recommendation was made to make such testing mandatory at the meeting. We believe blood collection centers will continue to focus on improving the safety of donated blood by adopting the most advanced blood screening technologies available. However, if 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.

Table of Contents

In the markets for clinical diagnostic products, a number of competitors, including Roche, Abbott, Becton Dickinson, Siemens and bioMérieux, currently compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. Our existing competitors or new market entrants may be in better position than we are to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners. Many of our competitors have, and in the future these and other competitors may have, significantly greater financial, marketing, sales, manufacturing, distribution and technological resources than we do. Moreover, these companies may have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do, any of which may adversely 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 polymerase chain reaction, or PCR, based NAT tests for blood screening in December 2002 and received FDA approval of a 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, 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, potentially accelerated by the world s macroeconomic conditions. 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, with whom we have a collaboration agreement for blood screening products, retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening using NAT. Prior to its merger with Novartis, Chiron granted HIV and HCV licenses to Roche in the blood screening and clinical diagnostics fields. Chiron also granted HIV and HCV licenses in the clinical diagnostics field to Bayer Healthcare LLC (now Siemens), together with the right to grant certain additional HIV and HCV sublicenses in the field to third parties. We believe Bayer s rights have now been assigned to Siemens as part of Bayer s December 2006 sale of its diagnostics business. Chiron also granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMérieux) in the clinical diagnostics field. If Novartis grants additional licenses in blood screening or Siemens grants additional licenses in clinical diagnostics, further competition will be created for sales of HCV and HIV assays and these licenses could affect the prices that can be charged for our products.

We have collaboration agreements to develop NAT products for industrial testing applications. We have limited experience operating in these markets and may not successfully develop commercially viable products.

We have collaboration agreements to develop NAT products for detecting microorganisms in selected water applications, and for microbiological and virus monitoring in the biotechnology and pharmaceutical manufacturing industries. We have limited experience applying our technologies and operating in industrial testing markets. The process of successfully developing products for application in these markets is expensive, time-consuming and unpredictable. Research and development programs to create new products require a substantial amount of our

scientific, technical, financial and human resources and there is no guarantee that new products will be successfully developed. We will need to design and execute specific product development plans in conjunction with our collaborative partners and make significant investments to ensure that any products we develop perform properly, are cost-effective and adequately address customer needs.

Table of Contents

Even if we develop products for commercial use in these markets, any products we develop may not be accepted in these markets, may be subject to competition and may be subject to other risks and uncertainties associated with these markets. For example, most pharmaceutical manufacturers rely on culture testing of their manufacturing systems, and may be unwilling to switch to molecular testing methods like that used in our recently launched MilliPROBE product to detect *Pseudomonas aeruginosa.* We have no experience with customer and customer support requirements, sales cycles, and other industry-specific requirements or dynamics applicable to these new markets and we and our collaborators may not be able to successfully convert customers to tests using our NAT technologies, which we expect will be more costly than existing methods. We will be reliant on our collaborators in these markets. Our interests may be different from those of our collaborators and conflicts may arise in these collaboration arrangements that have an adverse effect on our ability to develop new products. As a result of these risks and other uncertainties, we may not be able to successfully develop commercially viable products for application in industrial testing or any other new markets.

Failure to manufacture our products in accordance with product specifications could result in increased costs, lost revenues, customer dissatisfaction or voluntary product recalls, any of which could harm our profitability and commercial reputation.

Properly manufacturing our complex nucleic acid products requires precise technological execution and strict compliance with regulatory requirements. We may experience problems in the manufacturing process for a number of reasons, such as equipment malfunction or failure to follow specific protocols. If problems arise during the production of a particular product lot, that product lot may need to be discarded or destroyed. This could, among other things, result in increased costs, lost revenues and customer dissatisfaction. If problems are not discovered before the product lot is released to the market, we may incur recall and product liability costs. In the past, we have voluntarily recalled certain product lots for failure to meet product specifications. Any failure to manufacture our products in accordance with product specifications could have a material adverse effect on our revenues, profitability and commercial reputation.

Disruptions in the supply of raw materials and consumable goods or issues associated with the quality thereof from our single source suppliers, including Roche Molecular Biochemicals, which is an affiliate of one of our primary competitors, could result in a significant disruption in sales and profitability.*

We purchase some key raw materials and consumable goods used in the manufacture of our products from single-source suppliers. Certain of our key suppliers may be experiencing difficulties due to current economic conditions. 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 currently are involved in proceedings with Digene regarding our supply and purchase agreement with Roche Molecular Systems. Digene filed a demand for binding arbitration against Roche that challenged the validity of the supply and purchase agreement. Digene s demand 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. On April 1, 2009, following the arbitration hearing, the International Centre for Dispute Resolution, or ICDR, delivered the arbitrators interim award, which rejected all claims asserted by Digene (now Qiagen Gaithersburg, Inc.).

We have only one third-party manufacturer for each of our instrument product lines, which exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is the only manufacturer of our TIGRIS instrument. MGM Instruments, Inc. is the only manufacturer of our LEADER series of luminometers. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.

Table of Contents

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 our product commercialization as a result of, these regulations.*

The clinical diagnostic and blood screening products we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. We generally are prohibited from marketing our clinical diagnostic products in the United States unless we obtain either 510(k) clearance or premarket approval from the FDA. Delays in receipt of, or failure to obtain, clearances or approvals for future products could result in delayed, or no, realization of product revenues from new products or 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 (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, the number of subjects we will enroll in the trial is now expected to increase based on the actual prevalence of cervical disease among women already enrolled in the trial and other factors. In addition, we cannot guarantee that the FDA will ultimately approve the use of our APTIMA HPV assay upon completion of the trial. Failure to obtain FDA approval of our APTIMA HPV assay, or delays or difficulties experienced during the clinical trial, 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 clinical trial for the *Trichomonas* assay on the TIGRIS instrument system. We cannot guarantee that the assay will be approved for sale.

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 of 1988, 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 validated assay.

Table of Contents

We currently offer ASRs for use in the detection of PCA3 mRNA and for use in the detection of the parasite *Trichomonas vaginalis.* We also have developed an ASR for quantitative HCV testing that Siemens provides to Quest Diagnostics. In September 2007, the FDA published guidance for ASRs that define the types of products that can be sold as ASRs. Under the terms of this guidance and the ASR Manufacturer Letter issued in June 2008 by the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA, it may be more challenging for us to market some of our ASR products and we may be required to terminate those ASR product sales, conduct clinical studies and make submissions of our 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 that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some clinical laboratories from using some or all of our diagnostic products.

Certain of the industrial testing products that we intend to develop may be subject to government regulation, and market acceptance may be subject to the receipt of certification from independent agencies. We will be reliant on our industrial collaborators in these markets to obtain any necessary approvals. There can be no assurance that these approvals will be received.

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

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

The FDA and governmental bodies in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to product manufacturing, quality, labeling, advertising, or promotional activities, or if new information is obtained concerning the safety of a product. Our assay products incorporate complex biochemical reagents and our instruments comprise complex hardware and software. We have in the past voluntarily recalled products, which, in each case, required us to identify a problem and correct it. 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 by us, and any such recall could divert managerial and financial resources, could be more difficult and costly to correct, could result in the suspension of sales of our products and could harm our financial results and our reputation.

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

We currently receive revenues from the sale of blood screening assays primarily for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test. Since Novartis sells blood screening assays under our collaboration to blood collection 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 recently revised 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.

Table of Contents

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

Historically, a limited number of customers has accounted for a significant portion of our total revenues, and we do not have any long-term commitments with these customers, other than our collaboration agreement with Novartis. Revenues from our blood screening collaboration with Novartis accounted for 44% of our total revenues during the first six months of 2009 and 48% of our total revenues for 2008. 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 our total revenues for the first six months of 2009. Various state and city public health agencies accounted for an aggregate of 8% of our total revenues during the first six months of 2009 and 8% of total revenues for 2008. 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 development of blood screening and clinical diagnostic products and instruments. Although we had more than 490 United States and foreign patents covering our products and technologies as of June 30, 2009, 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 March 15, 2027 and the patents we may obtain in the future also will expire over time.

The scope of any of our issued patents may not be broad enough to offer meaningful protection. In addition, others may challenge our current patents or patents we may obtain in the future and, as a result, these patents could be narrowed, invalidated or rendered unenforceable, or we may be forced to stop using the technology covered by these patents or to license technology from third parties.

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

In addition to patent protection, we also rely on copyright and trademark protection, trade secrets, know-how, continued technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of our trade secrets and proprietary information, we require our employees, consultants, advisors and others to whom we disclose confidential information to execute confidentiality and proprietary information and inventions agreements. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, there may not be an adequate corrective remedy available. Furthermore, like many companies in our industry, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information and inventions agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these

individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market and execute our business strategies.

Table of Contents

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

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

Recently, we have been involved in a number of patent-related disputes with third parties. In December 2006, Digene filed a demand for binding arbitration against Roche with the ICDR of the American Arbitration Association in New York. Digene s demand 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. On April 1, 2009, following the arbitration hearing, the ICDR delivered the arbitrators interim award, which rejected all claims asserted by Digene (now Qiagen Gaithersburg, Inc.).

Pursuant to our June 1998 collaboration agreement with Novartis, we hold certain rights in the blood screening and clinical diagnostics fields under patents originally issued to Novartis covering the detection of HIV. We sell a qualitative HIV test in the clinical diagnostics field and we manufacture tests for HIV for use in the blood screening field, which Novartis sells under Novartis brands and name. In February 2005, the U.S. Patent and Trademark Office declared two interferences related to U.S. Patent No. 6,531,276 (Methods For Detecting Human Immunodeficiency Virus Nucleic Acid), originally issued to Novartis. The first interference was between Novartis and the National Institutes of Health, or NIH, and pertained to U.S. Patent Application No. 06/693,866 (Cloning and Expression of HTLV-III DNA). The second interference was between Novartis and Institut Pasteur, and pertained to Institut Pasteur s U.S. Patent Application No. 07/999,410 (Cloned DNA Sequences, Hybridizable with Genomic RNA of Lymphadenopathy-Associated Virus (LAV)). We are informed that the Patent and Trademark Office determined that Institut Pasteur invented the subject matter at issue prior to NIH and Novartis. We are also informed that Novartis and NIH subsequently filed actions in the United States District Court for the District of Columbia challenging the decisions of the Patent and Trademark Office in the patent interference cases. From November 2007 through June 2008, the parties engaged in settlement negotiations and then notified the court that they had signed a memorandum of understanding prior to the negotiation of final, definitive settlement documents. On May 16, 2008, we signed a license agreement with Institut Pasteur concerning Institut Pasteur s intellectual property for the molecular detection of HIV, covering products manufactured and sold through, and under, our brands or name. On June 27, 2008, the parties to the pending litigation in the United States District Court for the District of Columbia informed the court that they were unable to reach a final, definitive agreement and intended to proceed with litigation. There can be no assurances as to the ultimate outcome of the interference litigation and no assurances as to how the outcome of the interference litigation may affect the patent rights we licensed from Institut Pasteur, or Novartis right to sell HIV blood screening tests.

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 used $137.1 million of borrowings under the revolving credit facility to fund our acquisition of Tepnel and borrowed an additional $70.0

million under the revolving credit facility, bringing the total principal amount outstanding to $240.0 million as of June 30, 2009.

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 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 June 30, 2009, we had approximately $377.7 million of long-lived assets, including $12.9 million of capitalized software, net of accumulated amortization, relating to our TIGRIS and Panther instruments, goodwill of $90.7 million, a $5.4 million investment in Qualigen, Inc., or Qualigen, a $5.0 million investment in DiagnoCure, Inc., or DiagnoCure, and $110.0 million of capitalized licenses and manufacturing access fees, patents, purchased intangibles and other long term assets. Additionally, we had $73.4 million of land and buildings, $21.5 million of building improvements, $58.3 million of equipment and furniture and fixtures and $0.5 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. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

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

47

Table of Contents

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

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

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

We expect to continue to incur significant research and development expenses, which may make it difficult for us to maintain profitability.

In recent years, we have incurred significant costs in connection with the development of blood screening and clinical diagnostic products, 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 profitability. Although we expect our research and development expenses as a percentage of revenue to decrease in future periods, we may not be able to generate sufficient revenues to maintain profitability in the future. Our failure to maintain profitability in the future could cause the market price of our common stock to decline.

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

If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation and may contain other provisions that adversely affect the rights of the holders of our common stock. The terms of any debt securities may impose restrictions on our operations. If we raise funds through the issuance of equity or debt

convertible into equity, this issuance would result in dilution to our stockholders.

If we or our contract manufacturers are unable to manufacture our products in sufficient quantities, on a timely basis, at acceptable costs and in compliance with regulatory requirements, our ability to sell our products will be harmed.

Our products must be manufactured in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs and complying with regulatory requirements. In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on historical experience, inventory levels, current market trends and other related factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products we and our distributors require, which could harm our business and results of operations.

Table of Contents

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 or at a commercially reasonable cost, or at all. In addition, although we expect some of our newer products and products under development to share production attributes with our existing products, production of these newer products may require the development of new manufacturing technologies and expertise. We may be unable to develop the required technologies or expertise.

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

Blood screening and clinical diagnostic products are regulated by the FDA as well as other foreign medical regulatory bodies. In some cases, such as in the United States and the 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 23% of our total revenues during the first six months of 2009 and 23% of our total revenues for 2008. Sales by Novartis of collaboration blood screening products outside of the United States accounted for 64% of our international revenues during the first six months of 2009 and 78% in 2008. Novartis has responsibility for the international distribution of collaboration blood screening products.

We encounter risks inherent in international operations. We expect a significant portion of our sales growth, especially with respect to blood screening products, to come from expansion in international markets. If the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. In addition, our international sales have recently 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.

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

Table of Contents

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 reference laboratories, public health institutions and hospitals electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, these entities likely would purchase separate tests for each disease, rather than products that test for more than one microorganism.

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

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

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

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

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

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

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

person life insurance for any of our executive officers.

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

Table of Contents

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

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

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

Our research and development activities and our manufacturing activities involve the controlled use of infectious 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 by-laws, and provisions of Delaware law, could delay or prevent a change of control that our stockholders may favor.

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

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

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

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. If we fail to effectively manage our growth, it could adversely affect our ability to pursue business opportunities and expand our business.

Table of Contents

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, which could adversely affect our financial results, stock price and reputation.

Our forecasts and other forward looking statements are based upon various assumptions that are subject to significant uncertainties that may result in our failure to achieve our forecasted results.

From time to time in press releases, conference calls and otherwise, we may publish or make forecasts or other forward looking statements regarding our future results, including estimated earnings per share and other operating and financial metrics. Our forecasts are based upon various assumptions that are subject to significant uncertainties and any number of them may prove incorrect. For example, our revenue forecasts are based in large part on data and estimates we receive from our collaboration partners and distributors. Our achievement of any forecasts depends upon numerous factors, many of which are beyond our control. Consequently, our performance may not be consistent with management forecasts. Variations from forecasts and other forward looking statements may be material and could adversely affect our stock price and reputation.

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

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

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

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
April 1-30, 2009	52,277	$ 44.36	52,200	$ 137,087,871
May 1-31, 2009	1,549,900	43.64	1,549,900	69,453,161
June 1-30, 2009				69,453,161
Total[(1)(2)]	1,602,177	43.66	1,602,100	

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

(2) During the second quarter of 2009, we repurchased and retired 77 shares of our common stock, at an average price of $46.15, 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 June 30, 2009, we had an aggregate of 248,840 shares of restricted stock and 60,000 shares of deferred issuance restricted stock awards outstanding.

Table of Contents

Item 4. Submission of Matters to a Vote of Security Holders

On May 14, 2009, our Annual Meeting of Stockholders was held in San Diego, California for the following purposes:

(1) To elect three (3) nominees for director to hold office until the 2012 Annual Meeting of Stockholders.

For John W. Brown, the voting results were as follows:

For: 46,084,689
Against: 355,361
Abstain: 17,343

For John C. Martin, Ph.D, the voting results were as follows:

For: 46,107,476
Against: 332,696
Abstain: 17,222

For Henry L. Nordhoff, the voting results were as follows:

For: 45,836,829
Against: 605,549
Abstain: 15,015

(2) To approve an amendment to our 2003 Incentive Award Plan to increase the number of shares of common stock authorized for issuance thereunder by 2,500,000 shares. The voting results for this proposal were as follows:

For: 35,572,950
Against: 5,008,750
Abstain: 3,556,251

(3) To ratify the selection by the Audit Committee of our Board of Directors of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2009. The voting results for this proposal were as follows:

For: 43,500,858
Against: 2,941,616
Abstain: 14,920

(4) To approve, through a non-binding advisory vote, our Board of Directors proposed appointment of Carl W. Hull to our Board of Directors, effective May 18, 2009. The voting results for this proposal were as follows:

For: 46,330,927
Against: 97,680
Abstain: 28,787

No other matters were put to a vote at our 2009 Annual Meeting of Stockholders.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description
2.1(1)	Recommended Cash Offer for Tepnel Life Sciences plc.
2.2(2)	Implementation Agreement dated as of January 30, 2009 by and between Gen-Probe Incorporated and Tepnel Life Sciences plc.
3.1(3)	Form of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(4)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.3(5)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.4(6)	Certificate of Elimination of Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(3)	Specimen common stock certificate.
10.99	Amendment No. 2 to License, Development and Cooperation Agreement, effective as of April 28, 2009, between Gen-Probe Incorporated and DiagnoCure, Inc.**
10.100	Amended and Restated Employment Agreement, effective May 18, 2009, between Gen-Probe Incorporated and Carl W. Hull.
10.101	Form of Grant Notice and Deferred Issuance Restricted Stock Award Agreement between Gen-Probe Incorporated and Carl W. Hull.
10.102(7)	The 2003 Incentive Award Plan of Gen-Probe Incorporated, as adopted by the Board of Directors on March 20, 2009 and approved by stockholders on May 14, 2009.
31.1	Certification dated August 6, 2009, 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 August 6, 2009, 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 August 6, 2009, 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 August 6, 2009, 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 Current Report on Form 8-K filed with the SEC on January 30, 2009.

(2) Incorporated by reference to Gen-Probe s Current Report on Form 8-K filed with the SEC on February 5, 2009.

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

(4) Incorporated by reference to Gen-Probe s Quarterly Report on Form 10-Q for the

quarterly period ended June 30, 2004 filed with the SEC on August 9, 2004.

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

(6) 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.

(7) Incorporated by reference to Gen-Probe s Current Report on Form 8-K filed with the SEC on May 19, 2009.

Table of Contents

SIGNATURES

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

GEN-PROBE INCORPORATED

DATE: August 6, 2009

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

DATE: August 6, 2009

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