

HOLOGIC INC  
Form 10-Q  
August 02, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 23, 2012

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from            to

Commission File Number: 0-18281

**Hologic, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State of incorporation)

**04-2902449**  
(I.R.S. Employer

Identification No.)

**35 Crosby Drive,**

**Bedford, Massachusetts**  
(Address of principal executive offices)

**01730**  
(Zip Code)

**(781) 999-7300**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

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

As of July 26, 2012, 264,694,835 shares of the registrant's Common Stock, \$0.01 par value, were outstanding.

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**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements (unaudited)****HOLOGIC, INC.****CONSOLIDATED STATEMENTS OF INCOME****(Unaudited)****(In thousands, except per share data)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>June 23, 2012</b>	<b>June 25, 2011</b>	<b>June 23, 2012</b>	<b>June 25, 2011</b>
<b>Revenues:</b>				
Product sales	\$ 384,593	\$ 372,790	\$ 1,164,774	\$ 1,092,345
Service and other revenues	85,635	78,292	249,330	229,959
	470,228	451,082	1,414,104	1,322,304
<b>Costs and expenses:</b>				
Cost of product sales	134,062	129,141	420,429	385,863
Cost of product sales amortization of intangible assets	45,280	44,877	135,792	131,478
Cost of service and other revenues	46,246	42,503	137,763	124,981
Research and development	26,229	29,325	83,868	87,817
Selling and marketing	76,368	72,981	232,367	211,619
General and administrative	43,421	39,755	131,319	119,062
Amortization of intangible assets	15,733	14,794	47,204	43,842
Contingent consideration compensation expense	15,502	3,161	44,064	4,216
Contingent consideration fair value adjustments	(13,276)	629	35,034	(3,546)
Gain on sale of intellectual property, net			(12,424)	(84,502)
Litigation settlement charge			440	450
Restructuring and divestiture charges	136		828	
	389,701	377,166	1,256,684	1,021,280
Income from operations	80,527	73,916	157,420	301,024
Interest income	695	485	1,947	1,352
Interest expense	(25,593)	(28,673)	(83,614)	(85,767)
Loss on debt extinguishment			(42,347)	(29,891)
Other (expense) income, net	(622)	(1,304)	2,897	(938)
Income before income taxes	55,007	44,424	36,303	185,780
Provision for income taxes	31,413	8,228	32,170	56,199
Net income	\$ 23,594	\$ 36,196	\$ 4,133	\$ 129,581
<b>Net income per common share:</b>				
Basic	\$ 0.09	\$ 0.14	\$ 0.02	\$ 0.50

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Diluted	\$ 0.09	\$ 0.14	\$ 0.02	\$ 0.49
Weighted average number of shares outstanding:				
Basic	264,609	261,784	263,742	260,744
Diluted	267,294	265,167	266,359	264,114

See accompanying notes.

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**HOLOGIC, INC.**  
**CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(In thousands, except per share data)

	June 23, 2012	September 24, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 905,082	\$ 712,332
Restricted cash	524	537
Accounts receivable, less reserves of \$8,825 and \$6,516, respectively	336,437	318,712
Inventories	228,496	230,544
Deferred income tax assets	27,570	39,607
Prepaid income taxes	9,738	10,098
Prepaid expenses and other current assets	27,137	31,070
Total current assets	1,534,984	1,342,900
Property and equipment, net	232,746	238,666
Intangible assets, net	1,914,556	2,090,807
Goodwill	2,294,492	2,290,330
Other assets	50,016	46,077
Total assets	\$ 6,026,794	\$ 6,008,780
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 55,064	\$ 63,467
Accrued expenses	374,850	325,327
Deferred revenue	127,193	120,656
Total current liabilities	557,107	509,450
Convertible notes (principal of \$1,725,000)	1,542,146	1,488,580
Deferred income tax liabilities	844,154	957,426
Deferred service obligations - long-term	12,987	9,467
Other long-term liabilities	66,149	106,962
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.01 par value 1,623 shares authorized; 0 shares issued		
Common stock, \$0.01 par value 750,000 shares authorized; 264,885 and 262,459 shares issued, respectively	2,649	2,625
Capital in excess of par value	5,371,764	5,303,713
Accumulated deficit	(2,365,787)	(2,369,920)
Accumulated other comprehensive (loss) income	(2,857)	1,995
Treasury stock, at cost 219 shares	(1,518)	(1,518)
Total stockholders' equity	3,004,251	2,936,895

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Total liabilities and stockholders' equity	\$ 6,026,794	\$ 6,008,780
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See accompanying notes.

**Table of Contents****HOLOGIC, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(In thousands)**

	<b>Nine Months Ended</b>	
	<b>June 23, 2012</b>	<b>June 25, 2011</b>
<b>OPERATING ACTIVITIES</b>		
Net income	\$ 4,133	\$ 129,581
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	48,107	51,038
Amortization	182,996	175,320
Non-cash interest expense amortization of debt discount and deferred financing costs	54,882	57,363
Stock-based compensation expense	26,360	27,245
Excess tax benefit related to equity awards	(3,791)	(3,268)
Deferred income taxes	(124,253)	(35,346)
Gain on sale of intellectual property, net	(12,424)	(84,502)
Loss on debt extinguishment	42,347	29,891
Fair value adjustments to contingent consideration	35,034	(3,546)
Fair value write-up of inventory sold		3,298
Non-cash restructuring charges	16,435	
Impairment of cost-method equity investment		2,445
Loss on disposal of property and equipment	2,402	1,820
Other non-cash activity	(1,591)	(1,185)
Changes in operating assets and liabilities, net of acquisitions:		
Accounts receivable	(22,055)	12,120
Inventories	(8,959)	(34,731)
Prepaid income taxes	360	3,944
Prepaid expenses and other assets	1,356	1,358
Accounts payable	(8,155)	(8,361)
Accrued expenses and other liabilities	40,230	9,548
Deferred revenue	11,217	3,083
Net cash provided by operating activities	284,631	337,115
<b>INVESTING ACTIVITIES</b>		
Acquisition of business, net of cash acquired		(189,800)
Payment of additional acquisition consideration	(9,784)	(19,660)
Divestiture of business, net of cash transferred to the buyer		1,129
Purchase of property and equipment	(20,692)	(21,894)
Increase in equipment under customer usage agreements	(32,750)	(20,641)
Purchase of insurance contracts		(5,322)
Proceeds from sale of intellectual property	12,500	13,250
Purchase of other intangible assets		(3,021)
Purchase of cost-method investment	(250)	(99)
Other assets	(948)	385
Net cash used in investing activities	(51,924)	(245,673)
<b>FINANCING ACTIVITIES</b>		



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Payment of debt issuance costs	(7,908)	(5,327)
Repayments of notes payable		(1,015)
Contingent consideration payments	(51,680)	(4,295)
Net proceeds from issuance of common stock pursuant to employee stock plans	21,741	24,078
Excess tax benefit related to equity awards	3,791	3,268
Payment of employee restricted stock minimum tax withholdings	(5,707)	(10,394)
Net cash (used in) provided by financing activities	(39,763)	6,315
Effect of exchange rate changes on cash and cash equivalents	(194)	419
Net increase in cash and cash equivalents	192,750	98,176
Cash and cash equivalents, beginning of period	712,332	515,625
Cash and cash equivalents, end of period	\$ 905,082	\$ 613,801

See accompanying notes.

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**HOLOGIC, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

*(all tabular amounts in thousands except per share data)*

**(1) Basis of Presentation**

The consolidated financial statements of Hologic, Inc. (the Company) presented herein have been prepared pursuant to the rules of the Securities and Exchange Commission for quarterly reports on Form 10-Q and do not include all of the information and disclosures required by U.S. generally accepted accounting principles. These financial statements should be read in conjunction with the consolidated financial statements and notes thereto for the year ended September 24, 2011, included in the Company's Form 10-K filed with the Securities and Exchange Commission on November 23, 2011. In the opinion of management, the financial statements and notes contain all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the periods presented.

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from management's estimates if past experience or other assumptions do not turn out to be substantially accurate. Operating results for the three and nine months ended June 23, 2012 are not necessarily indicative of the results to be expected for any other interim period or the entire fiscal year ending September 29, 2012. Fiscal 2012 is a 53 week fiscal period.

During the fourth quarter of fiscal 2011, the Company reclassified compensation expense related to its Interlace Medical, Inc. (Interlace) acquisition from cost of product sales, research and development, selling and marketing and general administrative to a separate line item in its Consolidated Statements of Operations, contingent consideration compensation expense. For the three and nine months ended June 25, 2011, the aggregate amount of this reclassification was \$1.0 million and \$2.1 million, respectively.

*Subsequent Events Consideration*

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. There were no material recognized subsequent events recorded in the unaudited consolidated financial statements as of and for the three and nine months ended June 23, 2012.

On August 1, 2012, the Company completed its acquisition of Gen-Probe Incorporated (Gen-Probe) pursuant to the Agreement and Plan of Merger (Merger Agreement) entered into on April 29, 2012. See Note 3 for additional information.

**(2) Fair Value Measurements**

*Assets/Liabilities Measured and Recorded at Fair Value on a Recurring Basis*

As of June 23, 2012 and September 24, 2011, the Company's financial assets that are re-measured at fair value on a recurring basis included \$0.3 million in money market mutual funds in both periods that are classified as cash and cash equivalents in the Consolidated Balance Sheets. Money market funds are classified within Level 1 of the fair value hierarchy and are valued using quoted market prices for identical assets. The Company has a payment obligation under its Nonqualified Deferred Compensation Plan (DCP) to the participants of the DCP. This liability is recorded at fair value based on the underlying value of certain hypothetical investments as designated by each participant for their benefit. Since the value of the DCP obligation is based on market prices, the liability is classified within Level 1. In addition, the Company has contingent consideration liabilities related to its acquisitions that are recorded at fair value. The fair values of these liabilities are based on Level 3 inputs and are discussed in Notes 3 and 6(a).



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Assets and liabilities measured and recorded at fair value on a recurring basis consisted of the following at June 23, 2012:

	Fair Value at Reporting Date Using			
	Balance as of June 23, 2012	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 314	\$ 314	\$	\$
Total	\$ 314	\$ 314	\$	\$
Liabilities:				
DCP liability	\$ 23,707	\$ 23,707	\$	\$
Contingent consideration	82,936			82,936
Total	\$ 106,643	\$ 23,707	\$	\$ 82,936

The Company classifies its contingent consideration liabilities related to its acquisitions of Sentinelle Medical and Interlace within Level 3 of the fair value hierarchy because the fair value is determined using significant unobservable inputs. A reconciliation of the beginning and ending Level 3 contingent consideration liability is as follows:

	Three Months Ended		Nine Months Ended	
	June 23, 2012	June 25, 2011	June 23, 2012	June 25, 2011
Balance at beginning of period	\$ 96,212	\$ 111,925	\$ 103,790	\$ 29,500
Contingent consideration liabilities recorded at acquisition				86,600
Changes in fair value recorded to operating expenses	(13,276)	629	35,034	(3,546)
Payments		(4,295)	(55,888)	(4,295)
<b>Balance at end of period</b>	<b>\$ 82,936</b>	<b>\$ 108,259</b>	<b>\$ 82,936</b>	<b>\$ 108,259</b>

Payments of contingent consideration include amounts withheld from the former shareholders of Interlace pursuant to certain legal indemnification provisions and paid to other third-parties.

*Assets Measured and Recorded at Fair Value on a Nonrecurring Basis*

The Company remeasures the fair value of certain assets and liabilities upon the occurrence of certain events. Such assets comprise cost-method equity investments and long-lived assets, including property and equipment, intangible assets and goodwill.

The Company holds certain cost-method equity investments in non-publicly traded companies aggregating \$4.9 million and \$4.6 million at June 23, 2012 and September 24, 2011, respectively, which are included in other long-term assets on the Company's Consolidated Balance Sheets. These investments are generally carried at cost. Since the inputs utilized for the Company's periodic impairment assessment are not based on observable market data, these cost method equity investments are classified within Level 3 of the fair value hierarchy. To determine the fair value of these investments, the Company uses all available financial information related to the entities, including information based on recent or pending third-party equity investments in these entities. In certain instances, a cost method equity investment's fair value is not estimated as there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment and to do so would be impractical. During the three and nine months ended June 25, 2011, the Company recorded other-than-temporary impairment charges of \$0.3 million and \$2.4 million, respectively, related to one of these investments. There have been no such impairments in fiscal 2012.

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Refer to Note 5 for disclosure of the nonrecurring fair value measurement related to the debt extinguishment losses recorded in the second quarter of fiscal 2012 and the first quarter of fiscal 2011. Refer to Note 14 for disclosure of the nonrecurring fair value measurement related to the impairment charge recorded in the second quarter of fiscal 2012 for manufacturing equipment and equipment located at customer sites.

### *Disclosure of Fair Value of Financial Instruments*

The Company's financial instruments mainly consist of cash and cash equivalents, accounts receivable, cost-method equity investments, insurance contracts and related DCP liability, accounts payable and debt obligations. The carrying

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amounts of the Company's cash equivalents, accounts receivable and accounts payable approximate their fair value due to the short-term nature of these instruments. The carrying amount of the insurance contracts are recorded at the cash surrender value, as required by U.S. generally accepted accounting principles, which approximates fair value, and the related DCP liability is recorded at fair value. The Company believes the carrying amounts of its cost-method investments approximate fair value and has not performed an in-depth analysis of the fair values as it is not practical to do so.

The Company had \$1.54 billion and \$1.49 billion of Convertible Notes recorded (See Note 5) as of June 23, 2012 and September 24, 2011, respectively. The aggregate principal amount of the Convertible Notes at both periods was \$1.725 billion. On February 29, 2012, the Company entered into separate, privately-negotiated exchange agreements under which it retired \$500.0 million in aggregate principal of its 2007 Notes for \$500.0 million in aggregate principal of new 2.00% Convertible Senior Notes due 2042 ( 2012 Notes ). Subsequent to this transaction, the Company has three issues of Convertible Notes outstanding: 2007 Notes (principal of \$775.0 million), 2010 Notes (principal of \$450.0 million), and the 2012 Notes (principal of \$500.0 million). The fair value of the 2007 Notes, 2010 Notes and 2012 Notes as of June 23, 2012 was approximately \$762.4 million, \$467.6 million and \$452.5 million, respectively. The fair value of the 2007 Notes and 2010 Notes as of September 24, 2011 was approximately \$1.20 billion and \$468.7 million, respectively. The fair value of the Convertible Notes is based on quoted trading prices and represents a Level 1 measurement.

### **(3) Business Combinations**

#### **Gen-Probe Incorporated and Related Debt Financing**

On August 1, 2012, the Company completed the acquisition of Gen-Probe pursuant to the Merger Agreement entered into on April 29, 2012. Under the terms and conditions of the Merger Agreement, at the effective time and as a result of the acquisition, each share of common stock of Gen-Probe issued and outstanding immediately prior to the effective time of the acquisition was cancelled and converted into the right to receive \$82.75 in cash. The Company estimates the purchase price to be approximately \$4.0 billion, which was funded through available cash and financing consisting of senior secured credit facilities and Senior Notes discussed below. Given that the acquisition closed on August 1, 2012, the Company determined it was impracticable to provide all the disclosures required for a business combination pursuant to ASC 805, *Business Combinations*, and will do so in connection with filing its Form 10-K for fiscal 2012.

Gen-Probe, headquartered in San Diego, California, is a leader in molecular diagnostics products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility.

Concurrent with closing the Gen-Probe acquisition, on August 1, 2012, the Company and certain domestic subsidiaries (the Guarantors ) entered into a credit and guaranty agreement (the Credit Agreement ) with Goldman Sachs Bank USA, in its capacity as administrative and collateral agent, and the lenders party thereto (collectively, the Lenders ). Pursuant to the terms and conditions of the Credit Agreement, the Lenders have committed to provide senior secured financing in an aggregate amount of up to \$2.8 billion. On August 1, 2012, concurrently with the closing of the Gen-Probe acquisition, the Company borrowed \$2.5 billion aggregate principal under the Credit Agreement.

The Guarantors have guaranteed the Company's obligations under the credit facilities, and the credit facilities are secured by first-priority liens on, and a first-priority security interest in, substantially all of the assets of the Company and the Guarantors, including all of the capital stock of substantially all of the U.S. subsidiaries owned by the Company and the Guarantors, 65% of the capital stock of certain of the Company's first-tier foreign subsidiaries and all intercompany debt. The security interests are evidenced by a pledge and security agreement by and among Goldman Sachs Bank USA, as collateral agent, the Company and the Guarantors and other related agreements, including certain intellectual property security agreements and mortgages.

The credit facilities under the Credit Agreement consist of:

\$1.0 billion senior secured tranche A term loan, ( Term Loan A ) with a final maturity date of August 1, 2017;

\$1.5 billion secured tranche B term loan ( Term Loan B ) with a final maturity date of August 1, 2019; and

\$300.0 million secured revolving credit facility ( Revolving Facility ) with a final maturity date of August 1, 2017.

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The Company is required to make scheduled principal payments under Term Loan A in increasing amounts ranging from \$12.5 million per three month period beginning October 31, 2012 to \$50.0 million per three month period commencing October 31, 2015, and under Term Loan B in equal installments of \$3.75 million per three month period beginning on October 31, 2012 and for 27 three month periods thereafter. The remaining balance for each term loan is due at the maturity. Any amounts outstanding under the Revolving Facility are due at maturity. The Company is required to make principal repayments first, pro rata among the term loan facilities, and second to the Revolving Facility from specified excess cash flows from operations and from the net proceeds of specified types of asset sales, debt issuances, insurance recoveries and equity offerings. Subject to certain limitations, the Company may voluntarily prepay any of the credit facilities without premium or penalty.

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All amounts outstanding under the Credit Agreement will bear interest, at the Company's option, initially, with respect to all loans made under Term Loan A and the Revolving Facility: (i) at the Base Rate plus 2.00% per annum, or (ii) at the Adjusted Eurodollar Rate (i.e., the Libor rate) plus 3.00%, and with respect to loans made under Term Loan B: (i) at the Base Rate, with a floor of 2.00%, plus 2.50%, or (ii) at the Adjusted Eurodollar Rate, with a floor of 1.00% plus 3.50%. The applicable margin to the Base Rate or Eurodollar Rate on Term Loan A and the Revolving Facility are subject to specified changes depending on the total net leverage ratio as defined in the Credit Agreement. The Company will pay a quarterly commitment fee at an annual rate of 0.50% on the undrawn committed amount available under the Revolving Facility (which rate is subject to reduction depending on the total net leverage ratio as defined in the Credit Agreement).

The Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of the Company and the guarantors, subject to negotiated exceptions, to: incur additional indebtedness and additional liens on their assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. The credit facilities contain total net leverage ratio and interest coverage ratio financial covenants measured as of the last day of each fiscal quarter, as defined in the Credit Agreement.

The loan documents contain customary representations and warranties by the Company and the Guarantors, as well as customary events of default, including an event of default upon a change of control of the Company. An event of default will occur under the credit facilities if the Company, or in some circumstances one of the Guarantors, subject to the applicable cure periods, fails to make any payment when due under the loan documents, fails to comply with affirmative or negative covenants, makes a misrepresentation, defaults on other specified indebtedness, becomes subject to specified events of bankruptcy, fails to discharge specified judgments or orders of dissolution, or becomes subject to specified claims under ERISA. If an event of default occurs and is not cured within any applicable grace period or is not waived, the Lenders have the right to accelerate repayment of the indebtedness under the credit facilities to the extent provided in the loan documents and applicable law, and upon certain events of default concerning bankruptcy such acceleration shall occur automatically. If the Company's indebtedness evidenced by the credit facilities were accelerated, the Company and the Guarantors may not have sufficient funds to pay such indebtedness. In that event the Lenders would be entitled to enforce their security interests in the collateral securing such indebtedness, which will include substantially all of the assets of the Company and the Guarantors.

On August 1, 2012, the Company completed a private placement of \$1.0 billion aggregate principal amount of its 6.25% senior notes due 2020 (the Senior Notes) at an offering price of 100% of the aggregate principal amount of the Senior Notes. The Senior Notes were not registered under the Securities Act of 1933, as amended (the Securities Act), or any state securities laws, and were offered only to qualified institutional buyers in reliance on Rule 144A under the Securities Act and outside the United States in accordance with Regulation S under the Securities Act. The Senior Notes are general senior unsecured obligations of the Company and are guaranteed on a senior unsecured basis by the Guarantors.

On August 1, 2012, the Company and the Guarantors entered into an indenture with Wells Fargo Bank, National Association, as trustee, relating to the Senior Notes. The Senior Notes mature on August 1, 2020 and bear interest at the rate of 6.25% per year, payable semi-annually on February 1 and August 1 of each year, commencing on February 1, 2013.

The indenture contains covenants which limit, among other things, the Company's and certain of its subsidiaries' ability to incur additional indebtedness, pay dividends or repurchase or redeem capital stock, make certain investments, incur liens, enter into certain types of transactions with the Company's affiliates, and sell assets or consolidate or merge with or into other companies. These covenants are subject to a number of exceptions and qualifications.

The Company may redeem up to 35% of the aggregate principal amount of the Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before August 1, 2015, at a redemption price equal to 106.250% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date. The Company also has the option to redeem the Senior Notes on or after: August 1, 2015 through July 31, 2016 at 103.125% of par; August 1, 2016 through July 31, 2017 at 102.083% of par; August 1, 2017 through July 31, 2018 at 101.042% of par; and August 1, 2018 and thereafter at 100% of par. In addition, if the Company undergoes a change of control, as provided in the indenture, the Company will be required to make an offer to purchase each holder's Senior Notes at a price equal to 101% of the aggregate principal amount of the Senior Notes, plus accrued and unpaid interest, if any, to the repurchase date.

The indenture also contains certain customary events of default, including among others, failure to pay interest on the Senior Notes that continues for a period of 30 days after payment is due, failure to pay the principal of, or premium, if any, on the Senior Notes when due upon maturity, redemption, required repurchase, acceleration or otherwise, failure to comply with certain covenants and agreements after notice thereof, and certain events of bankruptcy or insolvency. An event of default under the indenture will allow the trustee or the holders of at least 25% in aggregate principal amount of the then-outstanding Senior Notes to declare to be immediately due and payable the principal amount of all such Senior Notes then outstanding, plus accrued but unpaid interest to the date of acceleration, or in the case of events of default involving



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bankruptcy or insolvency, such principal amount plus interest of all the Senior Notes shall become automatically due and payable immediately without any further action or notice.

On August 1, 2012, in connection with the issuance of the Senior Notes, the Company and the Guarantors entered into an exchange and registration rights agreement with the initial purchasers of the Senior Notes. Pursuant to the terms of the registration rights agreement, the Company and the Guarantors agreed to (i) file a registration statement covering an offer to exchange the Senior Notes for a new issue of identical exchange notes registered under the Securities Act on or before 180 days from August 1, 2012, (ii) use commercially reasonable efforts to cause such registration statement to become effective, and (iii) use commercially reasonable efforts to complete the exchange prior to 270 days after August 1, 2012. Under certain circumstances, the Company and the Guarantors may be required to provide a shelf registration statement to cover resales of the Senior Notes.

### **TCT International Co., Ltd.**

On June 1, 2011, the Company completed the acquisition of 100% of the equity interest in TCT International Co., Ltd. ( "TCT" ) and subsidiaries, a privately-held distributor of medical products, including the Company's ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT's operating subsidiaries are located in Beijing, China. The Company's acquisition of TCT has enabled it to obtain an established nationwide sales organization and customer support infrastructure in China, which is consistent with the Company's international expansion strategy. TCT has been integrated within the Company's international operations, and its results are primarily reported within the Company's Diagnostics reporting segment and to a lesser extent within the Company's GYN Surgical reporting segment from the date of acquisition. The Company concluded that the acquisition of TCT did not represent a material business combination, and therefore, no pro forma financial information has been provided herein.

The purchase price of \$148.4 million was comprised of \$135.0 million in cash, of which \$100.0 million was paid up-front and \$35.0 million plus a working capital adjustment \$13.2 million, was deferred for one year. In addition, \$0.9 million was paid in the first quarter of fiscal 2012 for additional assets acquired. The deferred payment was recorded on a present value basis of \$47.5 million in purchase accounting to reflect fair value and such payment was being accreted through interest expense over the one year deferral period. The \$35.0 million and a portion of the working capital adjustment of \$8.5 million were paid in the fourth quarter of fiscal 2012. As agreed to by the parties, the remainder is due after the completion of fiscal 2013. In addition, the majority of the former shareholders of TCT may receive two annual contingent earn-out payments (subject to adjustment) not to exceed \$200.0 million less the deferred payment. The contingent earn-out payments are based on a multiple of incremental revenue growth for the one year periods beginning January 1, 2011 and January 1, 2012 as compared to the respective prior year periods, and are payable after the first and second anniversaries from the date of acquisition, respectively. Since these payments are contingent on future employment, they are being recognized as compensation expense ratably over the required service periods, the first and second year anniversaries from the date of acquisition. Based on actual and projected revenues for the TCT business, the Company recorded compensation expense of \$15.0 million and \$42.6 million for the three and nine month periods ended June 23, 2012, respectively, and \$2.1 million for the three and nine month periods ended June 25, 2011. As of June 23, 2012, the Company has accrued \$60.1 million for these contingent payments, and \$54.0 million was paid in the fourth quarter of fiscal 2012 for the first earn out period.

The Company did not issue any equity awards in connection with this acquisition, and third-party transaction costs were immaterial.

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The allocation of the purchase price was based on estimates of the fair value of assets acquired and liabilities assumed as of June 1, 2011. The components of the purchase price allocation consisted as follows:

Cash	\$ 27,961
Accounts receivable	17,811
Inventory	5,301
Property and equipment	4,710
Other tangible assets	1,082
Accrued taxes	(14,874)
Accounts payable and accrued expenses	(6,641)
Customer relationships	45,780
Business licenses	2,500
Trade names	2,110
Deferred taxes, net	(12,473)
Goodwill	75,161
<b>Purchase Price</b>	<b>\$ 148,428</b>

In connection with the purchase price allocation, the Company determined that the separately identifiable intangible assets were customer relationships, business licenses, and trade names related to the TCT company name. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted at 12.5%. Customer relationships relate to relationships that TCT's founders and sales force have developed with obstetricians, gynecologists, hospitals, and clinical laboratories. Customer relationships, business licenses and trade names are being amortized over a weighted average period of 12.7 years, 10 years and 12 years, respectively. The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to the established sales and distribution network of TCT and expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

**Interlace Medical, Inc.**

On January 6, 2011, the Company consummated the acquisition of 100% of the equity interest in Interlace, a privately-held company located in Framingham, Massachusetts. Interlace is the developer, manufacturer and supplier of the MyoSure hysteroscopic tissue removal system ( MyoSure ). The MyoSure system is a tissue removal device that is designed to provide incision-less removal of fibroids and polyps within the uterus. Interlace's operations are reported within the Company's GYN Surgical reporting segment from the date of acquisition. The Company believes that MyoSure is a complementary product to its existing surgical product portfolio. The Company concluded that the acquisition of Interlace did not represent a material business combination, and therefore, no pro forma financial information has been provided herein.

The purchase price was comprised of \$126.8 million in cash ( Initial Consideration ), which was net of certain adjustments, plus two annual contingent payments up to a maximum of an additional \$225.0 million in cash. In addition to the Initial Consideration, \$2.1 million was paid to certain employees upon the completion of three and six months of service from the date of acquisition. Since these payments were contingent on future employment, they were recognized as compensation expense in fiscal 2011. The purchase agreement includes an indemnification provision that provides for the reimbursement of a portion of legal expenses in defense of the Interlace intellectual property. The Company has the right to collect certain amounts set aside in escrow from the Initial Consideration and, as applicable, offset contingent consideration payments of qualifying legal costs.

The contingent payments are based on a multiple of incremental revenue growth during a two-year period following the completion of the acquisition. Pursuant to Accounting Standards Codification ( ASC ) 805, *Business Combinations*, the Company recorded its estimate of the fair value of the contingent consideration liability based on future revenue projections of the Interlace business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 15.6%. The discount rate is based on the weighted-average cost of capital of the acquired business plus a credit risk premium for non-performance risk related to the liability pursuant to ASC 820. This analysis resulted in an initial contingent consideration liability of \$86.6 million, which is adjusted periodically as a component of operating expenses based on changes in fair value of the liability due to the accretion of the liability for the time value of money and changes in the assumptions pertaining to the achievement of the defined revenue growth milestones. This fair value measurement was based on significant inputs not observable in the market and thus represented a Level 3 measurement as defined in ASC 820. This fair value measurement is directly impacted by the



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Company's estimate of future incremental revenue growth of the business. Accordingly, if actual revenue growth is higher or lower than the estimates within the fair value measurement, the Company would record additional charges or benefits, respectively, as appropriate. The Company recorded a benefit of \$10.8 million and a charge of \$37.8 million for the three and nine month periods ended June 23, 2012, respectively, and \$3.3 million and \$6.0 million for the three and nine month periods ended June 25, 2011, respectively, for changes in the fair value of the contingent consideration liability. The fair value of the contingent consideration for the first measurement period was \$51.8 million. This payment was disbursed during the second quarter of fiscal 2012 of which \$47.6 million is reflected in the Consolidated Statements of Cash Flows as cash used in financing activities, representing the liability recognized at fair value for the first measurement period as of the acquisition date. The remainder, which is related to changes in the fair value of the liability, is reflected within cash provided by operating activities. As of June 23, 2012, the Company has accrued \$78.9 million for the second measurement period contingent payment.

The Company did not issue any equity awards in connection with this acquisition, and third-party transaction costs were immaterial.

The purchase price consideration was as follows:

Cash	\$ 126,798
Contingent consideration	86,600
<b>Total purchase price</b>	<b>\$ 213,398</b>

The allocation of the purchase price was based on estimates of the fair value of assets acquired and liabilities assumed as of January 6, 2011. The components of the purchase price allocation consisted as follows:

Cash	\$ 9,070
Inventory, including fair value adjustments	1,795
Other tangible assets	1,291
Accounts payable and accrued expenses	(1,988)
Developed technology	158,741
Trade names	1,750
Deferred taxes, net	(45,342)
Goodwill	88,081
<b>Purchase Price</b>	<b>\$ 213,398</b>

As part of the purchase price allocation, the Company determined that the separately identifiable intangible assets were developed technology and trade names related to the MyoSure product name. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted at 12.7%. Developed technology represented currently marketable Interlace products that the Company will continue to sell and utilize to enhance and incorporate into the Company's existing products. In determining the fair value of developed technology, consideration was only given to products that had been approved by the FDA. Based on the early stage of other projects and an insignificant allocation of resources to those projects, the Company concluded that there were no in-process projects of a material nature. Developed technology and trade names are being amortized over 15 years and 13 years, respectively. The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

**Beijing Healthcome Technology Company, Ltd.**

On July 19, 2011, the Company completed its acquisition of 100% of the equity in Beijing Healthcome Technology Company, Ltd. (Healthcome), a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China. Healthcome manufactured analog mammography products targeted to lower tier hospital segments in China. Additionally, Healthcome had been collaborating with the Company's research and development team to integrate its selenium detector technology into the Healthcome mammography platform. On December 21, 2011, the Company received SFDA approval in China for its Serenity digital mammography system.

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This acquisition provides the Company with manufacturing capability in China and additional access to the Chinese markets. The preliminary purchase price was \$9.8 million in cash, subject to adjustment. In addition, the Company is obligated to make future payments to the shareholders, who remain employed, up to an additional \$7.1 million over three years. Since these payments are contingent on future employment, they will be recognized as compensation expense ratably over the respective service periods. The Company recorded

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compensation expense of \$0.5 million and \$1.5 million in the three and nine month periods ended June 23, 2012, respectively. Healthcome's operations are reported within the Company's Breast Health reporting segment from the date of acquisition.

As part of the preliminary purchase price allocation, the Company determined that the separately identifiable intangible assets were developed technology of \$3.3 million, in-process research and development of \$0.9 million, and trade names of \$0.2 million. The in-process research and development project was completed in the first quarter of fiscal 2012. The Company is continuing to obtain information pertaining to certain acquired assets and liabilities, including tax assets and liabilities. The fair value of the intangible assets was determined through the application of the income approach, and the cash flow projections were discounted using rates ranging from 27% to 30%. Developed technology and trade names are being amortized over their useful lives of 13 and 7 years, respectively. The excess of the purchase price over the fair value of the tangible net assets and intangible assets acquired of \$7.0 million was recorded to goodwill. The goodwill recognized is attributable to expected synergies that the Company will realize from this acquisition. None of the goodwill is expected to be deductible for income tax purposes.

**(4) Other Balance Sheet Information**

	June 23, 2012	September 24, 2011
<b>Inventories</b>		
Raw materials	\$ 117,835	\$ 113,682
Work-in-process	26,848	30,217
Finished goods	83,813	86,645
	<b>\$ 228,496</b>	<b>\$ 230,544</b>
<b>Property and equipment</b>		
Equipment and software	\$ 233,169	\$ 223,403
Equipment under customer usage agreements	193,939	172,614
Building and improvements	58,629	58,937
Leasehold improvements	45,392	43,554
Furniture and fixtures	12,579	12,401
Land	8,630	8,883
	<b>552,338</b>	<b>519,792</b>
Less accumulated depreciation and amortization	(319,592)	(281,126)
	<b>\$ 232,746</b>	<b>\$ 238,666</b>

**(5) Debt***Convertible Notes*

On December 10, 2007, the Company issued and sold \$1.725 billion, at par, of 2.00% Convertible Senior Notes due 2037 (the "2007 Notes"). Net proceeds from the offering were \$1.69 billion, after deducting the underwriters' discounts and offering expenses, and were used to repay certain of the Company's outstanding senior secured indebtedness incurred in connection with the merger with Cytoc in fiscal 2008. The Company recorded the Convertible Notes net of the unamortized debt discount as required by U.S. generally accepted accounting principles. On November 18, 2010, the Company entered into separate, privately-negotiated exchange agreements under which it retired \$450.0 million in aggregate principal of its 2007 Notes for \$450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037 ("2010 Notes"). In connection with this exchange transaction, the Company recorded a loss on debt extinguishment of \$29.9 million in the first quarter of fiscal 2011. For additional information pertaining to the terms and provisions and related accounting for the 2007 Notes and 2010 Notes, refer to Note 5 to the consolidated financial statements contained in Item 15 of the Annual Report on Form 10-K for the year ended September 24, 2011.

On February 29, 2012, the Company entered into separate, privately-negotiated exchange agreements under which it retired \$500.0 million in aggregate principal of the 2007 Notes for \$500.0 million in aggregate principal of new 2.00% Convertible Senior Notes due 2042 ("2012 Notes").

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In connection with this exchange transaction, the Company recorded a loss on debt extinguishment of \$42.3 million in the second quarter of fiscal 2012. Following this transaction, \$775.0 million in principal amount of the 2007 Notes remain outstanding.

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Holders may require the Company to repurchase the 2012 Notes on any of March 1, 2018, March 1, 2022, March 1, 2027, March 1, 2032 and March 2, 2037 or upon a fundamental change, as provided in the indenture for the 2012 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest. The Company may redeem any of the 2012 Notes beginning March 6, 2018, by giving holders at least 30 days' notice. The Company may redeem the 2012 Notes either in whole or in part at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest, including contingent interest and liquidated damages, if any, to, but excluding, the redemption date.

The 2012 Notes bear interest at a rate of 2.00% per year on the principal amount, payable semi-annually in arrears in cash on March 1 and September 1 of each year, beginning September 1, 2012, and ending on March 1, 2018 and will accrete principal from March 1, 2018 at a rate that provides holders with an aggregate annual yield to maturity of 2.00% per year. Beginning with the six month interest period commencing March 1, 2018, the Company will pay contingent interest during any six month interest period to the holders of 2012 Notes if the trading price, as defined, of the 2012 Notes for each of the five trading days ending on the second trading day immediately preceding the first day of the applicable six month interest period equals or exceeds 120% of the accreted principal amount of the 2012 Notes. The holders of the 2012 Notes may convert the 2012 Notes into shares of the Company's common stock at a conversion price of \$31.175 per share, subject to adjustment, prior to the close of business on March 1, 2042, subject to prior redemption or repurchase of the 2012 Notes, under any of the following circumstances: (1) during any calendar quarter if the last reported sale price of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of such period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such day; (3) if the 2012 Notes have been called for redemption; or (4) upon the occurrence of specified corporate events. None of these triggering events had occurred as of June 23, 2012.

In lieu of delivery of shares of the Company's common stock in satisfaction of the Company's obligation upon conversion of the 2012 Notes, the Company may elect to deliver cash or a combination of cash and shares of its common stock. If the Company elects to satisfy its conversion obligation solely in cash, the Company is required to deliver cash in an amount as provided in the indenture for the 2012 Notes. If the Company elects to satisfy its conversion obligation in a combination of cash and shares of the Company's common stock, the Company is required to deliver up to a specified dollar amount of cash per \$1,000 original principal amount of 2012 Notes, and will settle the remainder of its conversion obligation in shares of its common stock, in each case based on the daily conversion value calculated as provided in the indenture for the 2012 Notes. In addition, at any time on or prior to the 35th scheduled trading day prior to the maturity date of the 2012 Notes, the Company may make an irrevocable election to settle conversions of the 2012 Notes either solely in cash or in a combination of cash and shares of our common stock with a specified cash amount at least equal to the accreted principal amount of the 2012 Notes. This net share settlement election is in the Company's sole discretion and does not require the consent of holders of the 2012 Notes. It is the Company's current intent and policy to settle any conversion of the 2012 Notes as if the Company had elected to make this net share settlement election.

The 2012 Notes are the Company's senior unsecured obligations and rank equally with all of its existing and future senior unsecured debt and prior to all future subordinated debt. The 2012 Notes are effectively subordinated to any future secured indebtedness to the extent of the collateral securing such indebtedness, and structurally subordinated to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

### *Accounting for the Convertible Notes*

The 2007 Notes, 2010 Notes and 2012 Notes were recorded pursuant to FASB Staff Position (FSP) APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1) (codified within ASC 470, *Debt*) since they can be settled in cash, or partially in cash, upon conversion. FSP APB 14-1 requires the liability and equity components of the convertible debt instrument to be separately accounted for in a manner that reflects the entity's nonconvertible debt borrowing rate when interest expense is subsequently recognized. The excess of the debt's principal amount over the amount allocated to the liability component is recognized as the value of the embedded conversion feature (equity component) within additional-paid-in capital in stockholders' equity and amortized to interest expense using the effective interest method. The liability component is initially recorded at its fair value, which is calculated using a discounted cash flow technique. Key inputs used to estimate the fair value of the liability component included the Company's estimated nonconvertible debt borrowing rate as of the measurement date (i.e. the date the Convertible Notes are issued), the amount and timing of cash flows, and the expected life of the Convertible Notes. In addition, third-party transaction costs are required to be allocated to the liability and equity components based on their relative values.



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The Company accounted for the retirement of the 2007 Notes, discussed above, under the derecognition provisions of subtopic ASC 470-20-40, which requires the allocation of the fair value of the consideration transferred (i.e., the 2012 Notes) between the liability and equity components of the original instrument to determine the gain or loss on the transaction. In connection with this transaction, the Company recorded a loss on debt extinguishment of \$42.3 million, which is comprised of the loss on the debt itself of \$39.7 million and the write-off of the pro-rata amount of debt issuance costs of \$2.6 million allocated to the notes retired. The loss on the debt itself is calculated as the difference between the fair value of the liability component of the 2007 Notes amount retired immediately before the exchange and its related carrying value immediately before the exchange.

The fair value of the liability component was calculated using a discounted cash flow technique with an effective interest rate of 2.89%, representing the estimated nonconvertible debt borrowing rate with a maturity as of the measurement date consistent with the 2007 Notes first put date of December 2013. In addition, under this accounting standard, a portion of the fair value of the consideration transferred is allocated to the reacquisition of the equity component, which is the difference between the fair value of the consideration transferred and the fair value of the liability component immediately before the exchange. As a result, on a gross basis, \$41.6 million was allocated to the reacquisition of the equity component of the original instrument, which is recorded net of deferred taxes within capital in excess of par value.

The 2012 Notes have the same characteristics as the 2007 Notes and 2010 Notes and can be settled in cash or a combination of cash and shares of common stock (i.e., partial settlement). As such, the Company is required to account for the liability and equity components of its 2012 Notes separately to reflect its nonconvertible debt borrowing rate. The Company estimated the fair value of the 2012 Notes liability component to be \$454.2 million using a discounted cash flow technique with an estimated effective interest rate of 3.72%, representing the estimated nonconvertible debt borrowing rate with a maturity as of the measurement date consistent with the 2012 Notes first put date of March 2018.

The excess of the fair value of the consideration transferred, which was estimated using a binomial lattice model, over the estimated fair value of the liability component of \$79.7 million was allocated to the embedded conversion feature as an increase to capital in excess of par value with a corresponding offset recognized as a discount to reduce the net carrying value of the 2012 Notes. The net debt discount of the 2012 Notes is being amortized to interest expense over a six-year period ending March 1, 2018 (the expected life of the liability component) using the effective interest method. In addition, third-party transaction costs have been allocated to the liability and equity components based on the relative values of these components.

As of June 23, 2012 and September 24, 2011, the Convertible Notes and related equity components (recorded in capital in excess of par value, net of deferred taxes) consisted of the following:

	June 23, 2012	September 24, 2011
2007 Notes principal amount	\$ 775,000	\$ 1,275,000
Unamortized discount	(61,154)	(147,287)
Net carrying amount	\$ 713,846	\$ 1,127,713
Equity component, net of taxes	\$ 233,353	\$ 259,000
2010 Notes principal amount	\$ 450,000	\$ 450,000
Unamortized discount	(78,122)	(89,133)
Net carrying amount	\$ 371,878	\$ 360,867
Equity component, net of taxes	\$ 60,054	\$ 60,054
2012 Notes principal amount	\$ 500,000	\$
Unamortized discount	(43,578)	
Net carrying amount	\$ 456,422	\$

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Equity component, net of taxes	\$ 49,195	\$
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Interest expense under the Convertible Notes was as follows:

	Three Months Ended		Nine Months Ended	
	June 23, 2012	June 25, 2011	June 23, 2012	June 25, 2011
Amortization of debt discount	\$ 15,119	\$ 18,229	\$ 52,018	\$ 54,438
Amortization of deferred financing costs	882	969	2,864	2,925
Non-cash interest expense	16,001	19,198	54,882	57,363
2.00% accrued interest	8,538	8,620	25,683	25,850
	\$ 24,539	\$ 27,818	\$ 80,565	\$ 83,213

If the Company fails to comply with the reporting obligations contained in the Convertible Notes agreements, the sole remedy of the holders of the Convertible Notes for the first 90 days following such event of default consists exclusively of the right to receive an extension fee in an amount equal to 0.25% of the accreted principal amount of the Convertible Notes. Based on the Company's evaluation of the Convertible Notes in accordance with ASC 815, *Derivatives and Hedging*, Subtopic 40, *Contracts in Entity's Own Equity*, the Company determined that the Convertible Notes contain a single embedded derivative, comprising both the contingent interest feature and the filing failure penalty payment, requiring bifurcation as the features are not clearly and closely related to the host instrument. The Company has determined that the value of this embedded derivative was nominal for all periods presented.

As of June 23, 2012, upon conversion, including the potential premium that could be payable on a fundamental change (as defined), the Company would issue a maximum of approximately 75.6 million common shares to the Convertible Note holders.

**(6) Commitments and Contingencies****(a) Contingent Earn-Out Payments**

In connection with its acquisitions, the Company has incurred the obligation to make contingent earn-out payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period. In certain circumstances, such as a change of control, a portion of these obligations may be accelerated. In addition, contractual provisions relating to these contingent earn-out obligations may include covenants to operate the businesses acquired in a manner that may not otherwise be most advantageous to the Company.

These contingent consideration arrangements are recorded as either additional purchase price or compensation expense if continuing employment is required to receive such payments. Pursuant to ASC 805, contingent consideration that is deemed to be part of the purchase price is recorded as a liability based on the estimated fair value of the consideration the Company expects to pay to the former shareholders of the acquired business as of the acquisition date. This liability is re-measured each reporting period with the changes in fair value recorded through a separate line item within the Company's Consolidated Statements of Operations. Increases or decreases in the fair value of contingent consideration liabilities can result from accretion of the liability for the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. Contingent consideration arrangements from acquisitions completed prior to the adoption of ASC 805 (effective in fiscal 2010 for the Company) that are deemed to be part of the purchase price of the acquisition are not subject to the fair value measurement requirements of ASC 805 and are recorded as additional purchase price to goodwill.

In connection with the acquisition of Adiana, Inc., the Company has an obligation to the former Adiana shareholders to make contingent payments tied to the achievement of milestones. The milestone payments include potential contingent payments of up to \$155.0 million based on worldwide sales of the Adiana Permanent Contraception System in the first year following FDA approval and on annual incremental sales growth thereafter through December 31, 2012. FDA approval of the Adiana system occurred on July 6, 2009, and the Company began accruing contingent consideration in the fourth quarter of fiscal 2009 based on the defined percentage of worldwide sales of the product. Since this contingent consideration obligation arose from an acquisition prior to the adoption of ASC 805, the amounts accrued are recorded as additional purchase price to goodwill. The purchase agreement includes an indemnification provision that provides for the reimbursement of qualifying legal expenses and liabilities associated with legal claims against the Adiana products and intellectual property, and the Company has the right to offset contingent consideration payments to the Adiana shareholders with these qualifying legal costs. The Company made payments of \$8.8 million and \$19.7 million in the first quarter of fiscal 2012 and 2011, respectively, to the former Adiana shareholders, net of amounts withheld for the legal indemnification provision. The Company had been in litigation with Conceptus regarding certain intellectual property matters

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related to the Aadiana system, and to the extent available, the Company has been recording legal fees related to the Conceptus litigation matter (described below) as a reduction to the accrued contingent consideration payments. No contingent consideration was earned and

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recorded in fiscal 2012, and as of the end of the second quarter of fiscal 2012 the Company decided to discontinue the manufacture, marketing and sales of the Adiana system. On October 17, 2011, the jury returned a verdict in the Conceptus litigation matter (see below) in favor of Conceptus awarding damages in the amount of \$18.8 million. On April 29, 2012, the Company entered into a license and settlement agreement with Conceptus in which Conceptus agreed to forgo the \$18.8 million jury award in consideration of the Company agreeing to a permanent injunction against the manufacture, sale and distribution of the Adiana product. At June 23, 2012, the Company has accrued \$18.8 million for the payment of contingent consideration to the former Adiana shareholders, which will be paid net of amounts withheld for qualifying legal costs.

In connection with the acquisition of Sentinelle Medical (acquired in the fourth quarter of fiscal 2010), the purchase agreement includes three contingent payments up to a maximum of an additional \$250.0 million in cash. The contingent payments are based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition as follows: six months after acquisition, 12 months after acquisition, and 24 months after acquisition. Pursuant to ASC 805, the Company recorded its estimate of the fair value of the contingent consideration liability based on future revenue projections of the Sentinelle Medical business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 16.5%. This analysis resulted in an initial contingent consideration liability of \$29.5 million. Each quarter, the Company re-evaluates its assumptions, including the revenue and probability assumptions for future earn-out periods, which has resulted in lower revenue projections. As a result of these adjustments, which were partially offset by the accretion of the liability, and using a current discount rate at that time of approximately 17.0%, the Company recorded a reversal of expense of \$14.3 million in fiscal 2011 to record the contingent consideration liability at its estimated fair value. The first two earn-out periods have lapsed, and the Company made payments of \$4.1 million and \$4.3 million in fiscal 2012 and 2011, respectively. In the third quarter of fiscal 2012, as a result of lowering its revenue projections for the Sentinelle business, the Company recorded a net benefit of \$2.5 million. At June 23, 2012, the fair value of this liability is \$4.0 million.

The Company also has contingent consideration obligations related to its Interlace, TCT and Healthcome acquisitions. Pursuant to ASC 805, contingent consideration pertaining to Interlace is required to be recorded as a liability at fair value. In the third quarter of fiscal 2012, as a result of lowering its revenue projections for the Interlace business, the Company recorded a net benefit of \$10.8 million to record the liability at its fair value of \$78.9 million as of June 23, 2012. During the second quarter of fiscal 2012, the first measurement period lapsed resulting in a total contingent consideration amount recorded for this period of \$51.8 million, which was disbursed to the former shareholders of Interlace, net of amounts withheld for certain legal indemnification purposes. Contingent consideration pertaining to TCT and Healthcome is contingent upon future employment and is being recorded as compensation expense as it is earned. As of June 23, 2012, the Company had accrued \$60.1 million and \$1.8 million, respectively, for these obligations. For additional information pertaining to the Interlace, TCT and Healthcome acquisitions, contingent consideration terms and the assumptions used to fair value contingent consideration, refer to Note 3.

A summary of amounts recorded to the Consolidated Statements of Operations is as follows:

Statement of Operations Line Item - 3 Months Ended June 23, 2012		Sentinelle Medical	Interlace	TCT	Healthcome	Total
Contingent consideration	compensation expense	\$	\$	\$ 15,013	\$ 489	\$ 15,502
Contingent consideration	fair value adjustments	(2,518)	(10,758)			(13,276)
		\$ (2,518)	\$ (10,758)	\$ 15,013	\$ 489	\$ 2,226

Statement of Operations Line Item - 9 Months Ended June 23, 2012		Sentinelle Medical	Interlace	TCT	Healthcome	Total
Contingent consideration	compensation expense	\$	\$	\$ 42,552	\$ 1,512	\$ 44,064
Contingent consideration	fair value adjustments	(2,728)	37,762			35,034
		\$ (2,728)	\$ 37,762	\$ 42,552	\$ 1,512	\$ 79,098

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Statement of Operations Line Item - 3 Months Ended June 25, 2011		Sentinel Medical	Interlace	TCT	Total
Contingent consideration	compensation expense	\$	1,047	\$ 2,114	\$ 3,161
Contingent consideration	fair value adjustments	(2,659)	3,288		629
		\$ (2,659)	\$ 4,335	\$ 2,114	\$ 3,790

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Statement of Operations Line Item - 9 Months Ended June 25, 2011		Sentinelle Medical	Interlace	TCT	Total
Contingent consideration	compensation expense	\$	\$ 2,102	\$ 2,114	\$ 4,216
Contingent consideration	fair value adjustments	(9,563)	6,017		(3,546)
		\$ (9,563)	\$ 8,119	\$ 2,114	\$ 670

**(b) Litigation and Related Matters**

On May 22, 2009, Conceptus, Inc. filed suit in the United States District Court for the Northern District of California seeking a declaration by the Court that Hologic's planned importation, use, sale or offer to sell of its forthcoming Adiana Permanent Contraception System would infringe five Conceptus patents. On July 9, 2009, Conceptus filed an amended complaint alleging infringement of the same five patents by the Adiana system. The complaint sought preliminary and permanent injunctive relief and unspecified monetary damages. In addition to the amended complaint, Conceptus also filed a motion for preliminary injunction seeking to preliminarily enjoin sales of the Adiana System based on alleged infringement of certain claims of three of the five patents. A hearing on Conceptus' preliminary injunction motion was held on November 4, 2009, and on November 6, 2009, the Court issued an order denying the motion. On January 19, 2010, upon stipulation of the parties, the Court dismissed all claims relating to three of the five asserted patents with prejudice. A Markman hearing on claim construction took place on March 10, 2010 and a ruling was issued on March 24, 2010. On April 12, 2010, in response to Hologic's counterclaims of unfair competition filed in October of 2009, the Court granted Conceptus leave to amend its counterclaims adding charges of unfair competition. On June 23, 2010, upon stipulation of the parties, the judge dismissed the asserted claims of an additional patent leaving three claims of U.S. patent 7,506,650 being asserted against the Company in the case. On August 10, 2010, the parties entered into a settlement agreement dismissing all unfair competition claims against each other. A hearing on both parties' motions for summary judgment on the patent claims occurred on December 9, 2010, and on December 16, 2010, a ruling was issued granting Hologic summary judgment of no infringement of one of the three asserted claims. A trial was held from October 3, 2011 through October 14, 2011 related to the asserted claims. On October 17, 2011 the jury returned a verdict in favor of Conceptus and awarded damages to Conceptus in the amount of \$18.8 million. Post trial motions were filed by both parties including a motion by Conceptus seeking to enjoin the Company from further sales of the Adiana system. A hearing on the post trial motions and injunction request took place on January 6, 2012, and on January 9, 2012, the judge issued an order denying Conceptus' motion for an injunction and further found that the Company will not be required to pay royalties on future sales of the Adiana system nor any supplemental damages. On January 19, 2012, the Court granted Hologic's motion to stay the payment of damages pending appeal. On February 8, 2012, Hologic filed a notice of appeal to overturn the jury verdicts related to infringement and validity. On the same day Conceptus filed a notice of appeal to overturn the Court's denial of the permanent injunction. On April 29, 2012, the Company entered into a license and settlement agreement with Conceptus in which Conceptus agreed to forgo the \$18.8 million jury award in consideration of the Company agreeing to a permanent injunction against the manufacture, sale and distribution of the Adiana product. The Company also granted Conceptus a license to Hologic's intellectual property related to the Adiana product.

On June 9, 2010, Smith & Nephew, Inc. filed suit against Interlace, which the Company acquired on January 6, 2011, in the United States District Court for the District of Massachusetts. In the complaint, it is alleged that the Interlace MyoSure hysteroscopic tissue removal device infringes U.S. patent 7,226,459. The complaint seeks permanent injunctive relief and unspecified damages. A Markman hearing was held November 9, 2010, and a ruling was issued on April 21, 2011. On November 22, 2011, Smith & Nephew, Inc. filed suit against the Company in the United States District Court for the District of Massachusetts. In the complaint, it is alleged that use of the MyoSure hysteroscopic tissue removal system infringes U.S. patent 8,061,359. The complaint seeks preliminary and permanent injunctive relief and unspecified damages. On January 17, 2012, at a hearing on Smith & Nephew's motion for preliminary injunction with respect to the suit filed November 22, 2011, the judge did not issue an injunction, consolidated the two matters for a single trial and scheduled a trial on the merits for both claims for June 25, 2012. A case management conference held on February 14, 2012 resulted in the trial being rescheduled to begin on August 20, 2012. On March 15, 2012, the Court heard summary judgment arguments related to the 459 patent and claim construction arguments related to the 359 patent. On June 5, 2012, the Court denied Smith & Nephew's request for summary judgment of infringement, denied Smith & Nephew's request for preliminary injunction, and denied Hologic's requests for summary judgment of non-infringement and invalidity. The trial remains scheduled for August 20, 2012. The purchase and sale agreement associated with the acquisition of Interlace includes an indemnification provision that provides for the reimbursement of a portion of legal expenses in defense of the Interlace intellectual property. The Company has the right to collect certain amounts set aside in escrow and, as applicable, offset contingent consideration payments of qualifying legal costs. The Company is recording legal fees incurred for this suit pursuant to the indemnification provision net within accrued expenses. At this time, the Company cannot determine the ultimate outcome of this litigation, or a reasonable estimate of the amount or range of possible loss.

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On February 10, 2012, C.R. Bard (as acquirer of SenoRx, Inc. SenoRx ) filed suit against the Company in the United States District Court of Delaware. In the complaint, it is alleged that our MammoSite product infringes SenoRx's U.S. Patents 8,079,946 and 8,075,469. The complaint seeks permanent injunctive relief and unspecified damages. At this time, the Company cannot determine the ultimate outcome of this litigation, or a reasonable estimate of the amount or range of possible loss.

On March 6, 2012, Enzo Life Sciences, Inc. ( Enzo ) filed suit against the Company in the United States District Court of Delaware. In the complaint, it is alleged that certain of the Company's molecular diagnostics products, including without limitation products based on our proprietary Invader chemistry such as Cervista HPV high risk and Cervista HPV 16/18, infringe Enzo's U.S. Patent 6,992,180. The complaint seeks permanent injunctive relief and unspecified damages. The Company was formally served with the complaint on July 3, 2012, but no hearing has been scheduled. At this time, the Company cannot determine the ultimate outcome of this litigation, or a reasonable estimate of the amount or range of possible loss.

A number of lawsuits have been filed against us, Gen-Probe Incorporated, and Gen-Probe's board of directors. These include: (1) Teamsters Local Union No. 727 Pension Fund v. Gen-Probe Incorporated, et al. (Superior Court of the State of California for the County of San Diego); (2) Timothy Coyne v. Gen-Probe Incorporated, et al. (Delaware Court of Chancery); and (3) Douglas R. Klein v. John W. Brown, et al. (Delaware Chancery Court). The two Delaware actions have been consolidated into a single action titled: In re: Gen-Probe Shareholders Litigation. The suits were filed after the announcement of the Gen-Probe Acquisition on April 30, 2012 as putative stockholder class actions. Each of the actions assert similar claims alleging that Gen-Probe's board of directors failed to discharge adequately its fiduciary duties to shareholders by failing to adequately value Gen-Probe's shares and ensure that Gen-Probe's shareholders received adequate consideration in our proposed acquisition of Gen-Probe, that the Gen-Probe Acquisition is the product of a flawed sales process, and that we aided and abetted the alleged breach of fiduciary duty. The plaintiffs demand, among other things, a preliminary and permanent injunction enjoining the Gen-Probe Acquisition and rescinding the transaction or any part thereof that has been implemented. On May 24, 2012, the plaintiffs in the Delaware action filed an amended complaint, adding allegations that the disclosures in Gen-Probe's preliminary proxy statement were inadequate. The defendants in the Delaware action answered the complaint on June 4, 2012. On July 18, 2012, the parties in the Delaware action entered into a memorandum of understanding regarding the settlement. The proposed settlement is conditioned upon, among other things, the execution of an appropriate stipulation of settlement, consummation of the merger, and final approval of the proposed settlement by the Delaware Court of Chancery. On May 21, 2012 and May 22, 2012, respectively, the defendants in the California action filed a motion to stay such action. On July 9, 2012, the plaintiffs in the California action filed for voluntary dismissal without prejudice. On July 12, 2012 the California Superior Court entered an order dismissing the California complaint without prejudice. At this time, the Company cannot determine the ultimate outcome of this litigation, or a reasonable estimate of the amount or range of possible loss.

The Company is a party to various other legal proceedings and claims arising out of the ordinary course of its business. The Company believes that except for those described above there are no other proceedings or claims pending against it the ultimate resolution of which would have a material adverse effect on its financial condition or results of operations. In all cases, at each reporting period, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under ASC 450, *Contingencies*. Legal costs are expensed as incurred.

**(7) Sale of Makena**

On January 16, 2008, the Company entered into an agreement to sell the full world-wide rights of its Makena (formerly Gestiva) pharmaceutical product to K-V Pharmaceutical Company ( KV ) upon FDA approval of the then pending Makena new drug application for \$82.0 million. The Company has executed certain amendments to this agreement resulting in an increase of the total sales price to \$199.5 million and changing when payments are due to the Company, which were based on obtaining FDA approval. Amounts received from KV of \$79.5 million prior to FDA approval were deferred.

On February 3, 2011, the Company received FDA approval of Makena, and subject to a security interest and a right of reversion for failure to make future payments, all rights to Makena were transferred to KV. Upon FDA approval, the Company received \$12.5 million, and including the \$79.5 million previously received, the Company recorded a gain on the sale of intellectual property, net of the write-off of certain assets, of \$84.5 million in the second quarter of fiscal 2011. Pursuant to the amended agreement, the Company received \$12.5 million in the second quarter of fiscal 2012, which has been recorded net of amounts due to the inventor of Makena. Currently, the remaining \$95.0 million of the sales price is due over a period of 18 to 30 months from FDA approval (subject to further deferral elections) depending on which one of two payment options KV selects. KV will also owe the Company a 5% royalty on sales for certain time periods determined based upon the payment option or deferral elections selected by KV.



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Due to uncertainty regarding collection, any amounts to be received in the future from KV have not been recorded in the Company's consolidated financial statements, and as the Company receives the amounts owed, the payments will be recorded as a gain within operating expenses in the Consolidated Statement of Operations in the period received.

**(8) Pension and Other Employee Benefits**

The Company has certain defined benefit pension plans covering the employees of its Hitec-Imaging German subsidiary (formerly AEG). As of June 23, 2012 and September 24, 2011, the Company has recorded a pension liability of \$7.5 million and \$8.1 million, respectively, primarily as a component of long-term liabilities in the Consolidated Balance Sheets. As of June 23, 2012 and September 24, 2011, the pension plans held no assets. Under German law, there is no minimum funding requirement imposed on employers. The Company's net periodic benefit cost and components thereof were not material during the three and nine months ended June 23, 2012 and June 25, 2011.

**(9) Net Income Per Share**

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus the dilutive effect of potential common shares from outstanding stock options, restricted stock units, the employee stock purchase plan, and convertible debt determined by applying the treasury stock method. In accordance with ASC 718, *Stock Compensation*, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of restricted stock units and stock options that are in-the-money based on the Company's average stock during the period.

The Company applies the provisions of ASC 260, *Earnings per Share*, Subtopic 10-45-44, to determine the diluted weighted average shares outstanding as it relates to its outstanding Convertible Notes, and due to the type of debt instrument issued, the Company uses the treasury stock method and not the if-converted method. The dilutive impact of the Company's Convertible Notes is based on the difference between the Company's current period average stock price and the conversion price of the Convertible Notes, provided there is a premium. Pursuant to this accounting standard, there is no dilution from the accreted principal of the Convertible Notes.

A reconciliation of basic and diluted share amounts is as follows:

	Three Months Ended		Nine Months Ended	
	June 23, 2012	June 25, 2011	June 23, 2012	June 25, 2011
<b>Numerator:</b>				
Net income	\$ 23,594	\$ 36,196	\$ 4,133	\$ 129,581
<b>Denominator:</b>				
Basic weighted average common shares outstanding	264,609	261,784	263,742	260,744
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock units	2,685	3,383	2,617	3,370
Diluted weighted average common shares outstanding	267,294	265,167	266,359	264,114
Basic net income per common share	\$ 0.09	\$ 0.14	\$ 0.02	\$ 0.50
Diluted net income per common share	\$ 0.09	\$ 0.14	\$ 0.02	\$ 0.49
<b>Weighted-average anti-dilutive shares related to:</b>				
Outstanding stock options	7,568	5,930	8,654	7,117
Restricted stock units			529	

Diluted weighted average shares outstanding do not include any effect resulting from the assumed conversion of the Company's Convertible Notes as their impact would be anti-dilutive for all periods presented.



**Table of Contents****(10) Stock-Based Compensation**

Share-based compensation expense is as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>June 23, 2012</b>	<b>June 25, 2011</b>	<b>June 23, 2012</b>	<b>June 25, 2011</b>
Cost of revenues	\$ 1,220	\$ 992	\$ 3,602	\$ 3,533
Research and development	1,210	1,081	3,688	3,633
Selling and marketing	1,840	1,342	5,234	4,486
General and administrative	4,484	4,364	13,836	15,593
	<b>\$ 8,754</b>	<b>\$ 7,779</b>	<b>\$ 26,360</b>	<b>\$ 27,245</b>

The Company granted approximately 2.1 million and 2.2 million stock options during the nine months ended June 23, 2012 and June 25, 2011, respectively, with weighted average exercise prices of \$17.09 and \$17.14, respectively. There were 15.3 million options outstanding at June 23, 2012 with a weighted average exercise price of \$17.48.

The Company uses a binomial model to determine the fair value of its stock options. The weighted-average assumptions utilized to value these stock options are indicated in the following table:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>June 23, 2012</b>	<b>June 25, 2011</b>	<b>June 23, 2012</b>	<b>June 25, 2011</b>
Risk-free interest rate	0.7%	1.0%	0.7%	1.0%
Expected volatility	47%	45%	47%	45%
Expected life (in years)	4.3	4.2	4.3	4.2
Dividend yield				
Weighted average fair value of options granted	\$ 7.10	\$ 7.96	\$ 6.43	\$ 6.23

The Company granted approximately 1.5 million and 1.2 million restricted stock units (RSU) during the nine months ended June 23, 2012 and June 25, 2011, respectively, with weighted average grant date fair values of \$17.09 and \$16.87, respectively. As of June 23, 2012, there were 3.5 million unvested RSUs outstanding with a weighted average grant date fair value of \$16.26.

The Company uses the straight-line attribution method to recognize stock-based compensation expense for stock options and RSUs. The vesting term of stock options granted to employees is generally five years with annual vesting of 20% per year on the anniversary of the grant date, and RSUs granted to employees generally vest over four years with annual vesting at 25% per year on the anniversary of the grant date. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that is ultimately expected to vest. Based on an analysis of historical forfeitures, the Company has determined a specific forfeiture rate for certain employee groups and has applied forfeiture rates ranging from 0% to 4.5% as of June 23, 2012. This analysis is periodically re-evaluated and forfeiture rates will be adjusted as necessary. Ultimately, the actual stock-based compensation expense recognized will only be for those stock options and RSUs that vest.

At June 23, 2012, there was \$31.7 million and \$40.0 million of unrecognized compensation expense related to stock options and RSUs, respectively, to be recognized over a weighted average period of 3.2 years and 2.6 years, respectively.

**(11) Comprehensive Income (Loss)**

The Company's other comprehensive income (loss) solely consists of foreign currency translation adjustments. A reconciliation of comprehensive income (loss) is as follows:

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	Three Months Ended		Nine Months Ended	
	June 23, 2012	June 25, 2011	June 23, 2012	June 25, 2011
Net income as reported	\$ 23,594	\$ 36,196	\$ 4,133	\$ 129,581
Translation adjustment	(9,528)	453	(4,852)	9,111
Comprehensive income (loss)	\$ 14,066	\$ 36,649	\$ (719)	\$ 138,692

**Table of Contents****(12) Business Segments and Geographic Information**

The Company reports segment information in accordance with ASC 280, *Segment Reporting*. Operating segments are identified as components of an enterprise for which separate, discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. The Company's chief operating decision maker is its chief executive officer, and the Company's reportable segments have been identified based on the types of products manufactured and the end markets to which the product are sold into. Each reportable segment generates revenue from either the sale of medical equipment and related services and/or the sale of disposable supplies, primarily used for diagnostic testing and surgical procedures. The Company has four reportable segments: Breast Health, Diagnostics, GYN Surgical and Skeletal Health. Certain reportable segments represent an aggregation of operating units within each segment. The Company measures and evaluates its reportable segments based on segment revenues and operating income adjusted to exclude the effect of non-cash charges, such as intangible asset amortization expense, contingent consideration charges, and other one-time or unusual items.

Identifiable assets for the four principal operating segments consist of inventories, intangible assets including goodwill, and property and equipment. The Company fully allocates depreciation expense to its four reportable segments. The Company has presented all other identifiable assets as corporate assets. There were no intersegment revenues during the three and nine months ended June 23, 2012 and June 25, 2011. Segment information is as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>June 23, 2012</b>	<b>June 25, 2011</b>	<b>June 23, 2012</b>	<b>June 25, 2011</b>
<b>Total revenues:</b>				
Breast Health	\$ 211,460	\$ 205,185	\$ 645,443	\$ 606,403
Diagnostics	158,710	143,446	464,615	420,777
GYN Surgical	77,672	79,353	233,395	226,526
Skeletal Health	22,386	23,098	70,651	68,598
	\$ 470,228	\$ 451,082	\$ 1,414,104	\$ 1,322,304
<b>Operating income (loss):</b>				
Breast Health	\$ 48,910	\$ 47,230	\$ 145,196	\$ 132,365
Diagnostics	11,466	24,052	53,223	157,149
GYN Surgical	17,740	(483)	(50,650)	2,660
Skeletal Health	2,411	3,117	9,651	8,850
	\$ 80,527	\$ 73,916	\$ 157,420	\$ 301,024
<b>Depreciation and amortization:</b>				
Breast Health	\$ 10,594	\$ 10,366	\$ 31,668	\$ 30,344
Diagnostics	40,382	40,452	120,297	120,218
GYN Surgical	25,520	23,474	77,825	66,994
Skeletal Health	443	2,861	1,313	8,802
	\$ 76,939	\$ 77,153	\$ 231,103	\$ 226,358
<b>Capital expenditures:</b>				
Breast Health	\$ 2,691	\$ 1,815	\$ 6,473	\$ 9,592
Diagnostics	11,016	6,433	28,640	17,906
GYN Surgical	4,138	3,419	10,138	8,302
Skeletal Health		1,083	198	2,133
Corporate	2,040	2,098	7,993	4,602

\$ 19,885	\$ 14,848	\$ 53,442	\$ 42,535
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	June 23, 2012	September 24, 2011
Identifiable assets:		
Breast Health	\$ 967,983	\$ 985,196
Diagnostics	1,680,094	1,770,107
GYN Surgical	1,975,877	2,049,682
Skeletal Health	32,279	31,864
Corporate	1,370,561	1,171,931
	\$ 6,026,794	\$ 6,008,780

The Company had no customers with balances greater than 10% of accounts receivable as of June 23, 2012 or September 24, 2011, or any customer that represented greater than 10% of product revenues during the three and nine months ended June 23, 2012 and June 25, 2011.

The Company operates in the major geographic areas as noted in the below chart. Revenue data is based upon customer location, and internationally totaled \$125.1 million and \$359.1 million during the three and nine months ended June 23, 2012, respectively, and \$104.5 million and \$298.7 million during the three and nine months ended June 25, 2011, respectively. Other than the United States, no single country accounted for more than 10% of consolidated revenues. The Company's sales in Europe are predominantly derived from Germany, the United Kingdom and the Netherlands. The Company's sales in Asia-Pacific are predominantly derived from China, Australia and Japan. The All others designation includes Canada, Latin America and the Middle East. Products sold by the Company internationally are manufactured at both domestic and international locations.

Revenues by geography as a percentage of total revenues are as follows:

	Three Months Ended		Nine Months Ended	
	June 23, 2012	June 25, 2011	June 23, 2012	June 25, 2011
United States	73%	77%	75%	77%
Europe	12%	14%	12%	14%
Asia	10%	5%	8%	5%
All others	5%	4%	5%	4%
	100%	100%	100%	100%

**(13) Income Taxes**

In accordance with ASC 740, *Income Taxes*, each interim period is considered integral to the annual period and tax expense is measured using an estimated annual effective rate. The Company records income tax expense each quarter based on its best estimate of the annual effective rate for the full fiscal year and uses that rate to provide for income taxes on a current year-to-date basis, as adjusted for discrete taxable events that occur during the interim period.

The Company's effective tax rates for the three and nine month periods ended June 23, 2012 were 57.1% and 88.6%, respectively, compared to 18.5% and 30.3%, respectively, for the corresponding periods in the prior year. For the three and nine months ended June 23, 2012, the effective tax rates were higher than the statutory rate primarily due to non-deductible contingent consideration compensation expense related to TCT, fair value adjustments related to the Interlace and Sentinelle Medical contingent consideration liabilities, and state taxes. The Company also established a \$2.6 million valuation allowance for Canadian tax credits due to uncertainties surrounding its ability to generate future taxable income to fully utilize these tax assets. For the three months ended June 25, 2011, the effective tax rate was less than the statutory rate primarily due to reversing \$8.2 million in income tax reserves due to settling the United States Internal Revenue Service (the IRS) federal audit for fiscal years 2007, 2008 and 2009 and the statute of limitations expiring in various federal, state and foreign jurisdictions, and the Section 199 manufacturing deduction. For the nine months ended June 25, 2011, the effective tax rate was less than the statutory rate primarily due to the Section 199 manufacturing deduction, reversal of income tax reserves, U.S. and Canadian research credits, the retroactively reinstated Federal research credit, and the tax benefit generated from the debt extinguishment loss recorded in the first quarter of fiscal 2011.

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As of June 23, 2012, the Company has recorded \$816.6 million of net deferred tax liabilities, which is net of certain deferred tax assets, compared to \$917.8 million at September 24, 2011. The Company's deferred tax assets are periodically evaluated to determine their recoverability. In connection with retiring \$500.0 million principal of the 2007 Notes, the



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Company is required to recapture the original issuance discount it deducted for tax purposes and remit \$59.0 million to the Internal Revenue Service and state taxing jurisdictions in fiscal 2012. This amount had been recorded within the deferred tax liabilities.

The Company has \$30.6 million of gross unrecognized tax benefits, including interest, at June 23, 2012. This represents the unrecognized tax that, if recognized, would reduce the Company's effective tax rate. The Company's policy is to recognize accrued interest and penalties related to unrecognized tax benefits and income tax liabilities within income tax expense. As of June 23, 2012, accrued interest is \$0.9 million, net of federal benefit, and no penalties have been accrued.

**(14) Restructuring and Divestiture Actions**

At the end of the second quarter of fiscal 2012, the Company decided to cease manufacturing, marketing and selling its Adiana system, which is a product line within the Company's GYN Surgical reporting segment, determining that the product was not financially viable and would not become so in the foreseeable future. As a result, in the second quarter of fiscal 2012, the Company recorded a charge of \$18.3 million of which \$17.9 million was recorded within cost of product sales and \$0.4 million was recorded in restructuring. The amount recorded in cost of product sales comprised impairment charges of \$9.2 million to record inventory at its net realizable value and \$6.1 million to write down certain manufacturing equipment and equipment placed at customer sites to its fair value that had no further utility, and \$2.6 million for outstanding contractual purchase orders of raw materials and components related to the Adiana system that will not be utilized. In connection with this action, the Company terminated certain manufacturing and other personnel primarily at its Costa Rica location, resulting in severance charges of \$0.2 million, and other contractual charges of \$0.2 million. In the third quarter of fiscal 2012, the Company recorded additional charges of \$1.7 million related to this action resulting from changes in certain estimates. The Company recorded \$1.5 million in cost of product sales comprised of impairment charges of \$1.1 million for the write-off of inventory and additional equipment, and \$0.4 million for purchase orders and other contractual obligations, and \$0.2 million recorded in restructuring for certain contractual obligations partially offset by lower severance incurred. All identified employees were terminated and paid as of June 23, 2012.

The following table displays the charges and adjustments related to this action as of June 23, 2012:

Statement of Operations	Second Quarter	Third Quarter	Total
Non-cash impairment charge	\$ 15,316	\$ 1,119	\$ 16,435
Purchase orders and other contractual obligations	2,761	646	3,407
Severance	207	(69)	138
Total	\$ 18,284	\$ 1,696	\$ 19,980

The following is a rollforward of the charges and amounts paid and accrued as of June 23, 2012:

Total charges recorded	\$ 19,980
Non-cash impairment charges	(16,435)
Severance payments	(138)
Purchase orders and other contractual obligations payments	(1,166)
Balance at June 23, 2012	\$ 2,241

During the second quarter of fiscal 2012, the Company abandoned certain lease space and recorded charges of \$0.4 million to terminate the leases and write-off related leasehold improvements that have no further utility. The obligation to the landlord was paid in the third quarter of fiscal 2012.

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During the third quarter of fiscal 2012, the Company finalized its decision to consolidate its Selenium panel coating process and transfer the production line to its Newark, Delaware facility in the United States from its Hitec-Imaging German subsidiary. The transfer is expected to be completed in the second half of fiscal 2013. In connection with this consolidation plan, the Company expects to terminate certain employees, primarily manufacturing personnel. Severance charges will be

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recorded pursuant to ASC 420, *Exit or Disposal Cost Obligations*, because the severance benefits qualify as one-time employee termination benefits, which are currently being negotiated between the Company and the local works council on behalf of the employees. Since the benefit amount is not fixed nor has any severance benefit been communicated to the affected employees, no charge has been recorded as of June 23, 2012. Employees must continue to be employed by the Company until their employment is involuntarily terminated in order to receive the severance benefit. As such, the severance benefit will be recognized ratably over the required service period.

**(15) Goodwill and Intangible Assets*****Goodwill***

In accordance with ASC 350, *Intangibles-Goodwill and Other*, the Company tests goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business, and an adverse action or assessment by a regulator. The Company conducts its annual goodwill impairment test as of the first day of its fiscal fourth quarter.

The Company conducted its fiscal 2011 annual impairment test on the first day of the fourth quarter. The Company utilized the income approach under the discounted cash flow method ( DCF ) and market approaches to estimate the fair value of its reporting units as of June 26, 2011, and ultimately used the fair value determined by the DCF in making its impairment test conclusions. The Company believes it used reasonable estimates and assumptions about future revenue, cost projections, cash flows and market multiples. In addition, using a DCF requires the use of a risk-adjusted discount rate for which the Company based its rate on the weighted average cost of capital ( WACC ) of market participants. As a result of completing Step 1, all of the Company's reporting units had fair values exceeding their carrying values, and as such, Step 2 of the impairment test was not required. For illustrative purposes, had the fair value of each reporting unit been lower by 10%, each reporting unit would have still passed Step 1 of the goodwill impairment test.

The Company previously had ongoing litigation with Conceptus regarding potential patent infringement of a Conceptus patent by the Company's Adiana system. In the first quarter of fiscal 2012, the jury returned a verdict in favor of Conceptus and awarded Conceptus \$18.8 million in damages. Post trial motions were filed, and Conceptus sought to enjoin the Company from further sales of the Adiana system. The Company was appealing the jury verdict, and all trial and post trial rulings were subject to appeal by either party. See note 6(b) for additional discussion of this litigation matter. The jury verdict in the first quarter of fiscal 2012 and related subsequent litigation status was an indicator of impairment for the Company's GYN Surgical reporting unit, and a reduction in the anticipated future cash flows of the GYN Surgical reporting unit could result in a material impairment charge. Accordingly, the Company performed an interim goodwill impairment analysis as of December 24, 2011, updating its cash flow projections and related assumptions from its fiscal 2011 annual impairment test, including the WACC, under various potential scenarios. The Company applied the weighted average probability approach to these scenarios to estimate the fair value of the GYN Surgical reporting unit. As a result of completing Step 1, GYN Surgical's fair value exceeded its carrying value. Therefore, Step 2 of the impairment test was not required as of December 24, 2011. The Company believed it used reasonable estimates and assumptions about future revenue, cost projections, cash flows, probabilities of cash flow scenarios, and market multiples as of that measurement date.

In connection with the Company's decision to discontinue the Adiana product line in the second quarter of fiscal 2012 discussed above, and its updated forecast for the GYN Surgical reporting unit in which the estimate of NovaSure revenues from previous analyses has decreased over the next few years, the Company concluded that potential goodwill impairment indicators existed as of March 24, 2012. As such, the Company performed an interim goodwill impairment test as of March 24, 2012, updating its cash flow projections and related assumptions from the analysis performed as of December 24, 2011. As a result of completing Step 1, GYN Surgical's fair value exceeded its carrying value. Therefore, Step 2 of the impairment test was not required as of March 24, 2012. The Company believes it used reasonable estimates and assumptions about future revenue, cost projections, cash flows, probabilities of cash flow scenarios, and market multiples as of that measurement date.

The following table presents the changes in goodwill during the nine months ended June 23, 2012:

Balance at September 24, 2011	\$ 2,290,330
Adjustments, including taxes	4,036
Foreign currency translation impact	126
Balance at June 23, 2012	\$ 2,294,492



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The allocation of goodwill by reporting segment consisted of the following:

	Balance as of June 23, 2012	Balance as of September 24, 2011
Breast Health	\$ 640,029	\$ 638,887
Diagnostics	630,396	633,319
GYN Surgical	1,015,955	1,009,973
Skeletal Health	8,112	8,151
	\$ 2,294,492	\$ 2,290,330

**Intangible Assets**

The Company amortizes its intangible assets that have definite lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. Amortization is recorded over the estimated useful lives ranging from 2 to 30 years.

The Company evaluates the realizability of its definite-lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of undiscounted future cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets, generally utilizing a DCF based on market participant assumptions pursuant to ASC 820. The Company would record an impairment charge to the extent the carrying value of the assets exceeds their fair value.

During the first and second quarters of fiscal 2012, as a result of the Company's conclusion that an interim impairment test of goodwill was required for its GYN Surgical reporting unit, the Company also performed an impairment test of the reporting unit's long-lived assets as of December 24, 2011 and March 24, 2012. The impairment evaluation was based on expectations of future undiscounted cash flows compared to the carrying value of the long-lived asset group. The Company believes that its procedures for estimating future cash flows were reasonable and consistent with market conditions at the time of estimation. The results of the Company's interim impairment testing indicated that there was no impairment of its long-lived assets.

Intangible assets consisted of the following:

Description	As of June 23, 2012		As of September 24, 2011	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Developed technology	\$ 2,216,873	\$ 722,011	\$ 2,215,323	\$ 586,647
In-process research and development			840	
Customer relationships	512,170	186,035	507,974	150,039
Trade names	142,987	55,051	142,799	44,267
Patents	11,088	7,850	9,937	7,752
Business licenses	2,545	271	2,535	81
Non-competition agreements	297	186	297	112
Totals	\$ 2,885,960	\$ 971,404	\$ 2,879,705	\$ 788,898

Amortization expense related to developed technology and patents is classified as a component of cost of product sales amortization of intangible assets in the Consolidated Statements of Operations. Amortization expense related to customer relationships, trade names, business licenses and non-competition agreements is classified as a component of amortization of intangible assets in the Consolidated Statements of Operations.

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The estimated remaining amortization expense as of June 23, 2012 for each of the five succeeding fiscal years is as follows:

Remainder of Fiscal 2012	\$ 60,800
Fiscal 2013	232,301
Fiscal 2014	217,761
Fiscal 2015	202,839
Fiscal 2016	189,019

**Table of Contents****(16) Product Warranties**

The Company generally offers a one-year warranty for its products. The Company provides for the estimated cost of fulfilling its product warranty obligations at the time product revenue is recognized. Factors that affect the Company's warranty reserves include the number of units sold, historical and anticipated rates of warranty repairs and the cost per repair. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary.

Product warranty activity is as follows:

	Balance at Beginning of Period	Provisions	Acquired	Settlements/ Adjustments	Balance at End of Period
Nine Months Ended:					
June 23, 2012	\$ 4,448	\$ 5,632	0	\$ (5,150)	\$ 4,930
June 25, 2011	\$ 2,830	\$ 3,792	657	\$ (3,071)	\$ 4,208

**(17) New Accounting Pronouncements***Disclosures about Offsetting Assets and Liabilities*

In December 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 amended ASC 210, *Balance Sheet*, to converge the presentation of offsetting assets and liabilities between U.S. GAAP and IFRS. ASU 2011-11 requires that entities disclose both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. ASU 2011-11 is effective for fiscal years, and interim periods within those years, beginning after January 1, 2013, which is the Company's fiscal year 2014. The Company is currently evaluating the impact of the adoption of ASU 2011-11 on its consolidated financial statements.

*Presentation of Comprehensive Income*

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 is effective for the Company in its first quarter of fiscal 2013 and should be applied retrospectively. The Company is currently evaluating the impact of the adoption of ASU 2011-05 on its consolidated financial statements.

*Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements*

In May 2011, the FASB issued ASU No. 2011-04 *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 is effective for the Company in its second quarter of fiscal 2012 and should be applied prospectively. The adoption of ASU 2011-04 did not have a material impact on the Company's consolidated financial statements.

*Business Combinations*

In December 2010, the FASB issued ASU No. 2010-29, *Business Combinations (ASC Topic 805) Disclosure of Supplementary Pro Forma Information for Business Combinations*. ASU 2010-29 requires a public entity to disclose revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the prior year. It also requires a description of the nature and amount of material, nonrecurring adjustments directly attributable to the business combination included in the reported revenue and earnings. The new disclosure was effective for the Company's first quarter of fiscal 2012 and did not have a material impact on the

Company's consolidated financial statements.



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### *Intangibles Goodwill and Other*

In December 2010, the FASB issued ASU 2010-28, *Intangibles Goodwill and Other (ASC Topic 350)*. ASU 2010-28 modifies Step 1 of the goodwill impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. ASU 2010-28 is effective for the Company in fiscal 2012. The Company does not believe that ASU 2010-28 will have a material impact on its consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. ASU 2011-08 allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. ASU 2011-08 is effective for the Company beginning in fiscal 2013, although early adoption is permitted. The Company does not believe that ASU 2011-08 will have a material impact on its consolidated financial statements.

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

### **CAUTIONARY STATEMENT**

Some of the statements contained in this report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements involve known and unknown risks, uncertainties and other factors which may cause our or our industry's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding:

the effect of the continuing worldwide macroeconomic uncertainty on our business and results of operation;

the coverage and reimbursement decisions of third party payors relating to the use of our products and treatments;

the uncertainty of the impact of cost containment efforts and federal healthcare reform legislation, including the excise tax on the sale of most medical devices, on our business and results of operation;

the impact and anticipated benefits of the acquisition of Gen-Probe and the challenges associated with successfully integrating and operating the Gen-Probe business;

the impact and anticipated benefits of recently completed acquisitions and acquisitions we may complete in the future;

our goal of expanding our market positions;

the development of new competitive technologies and products;

regulatory approval and clearances for our products;

production schedules for our products;

the anticipated development of our markets and the success of our products in these markets;

the anticipated performance and benefits of our products;

business strategies;

estimated asset and liability values;

the impact and costs and expenses of any litigation we may be subject to now or in the future;

compliance with covenants contained in our indebtedness;

anticipated trends relating to our financial condition or results of operations; and

our capital resources and the adequacy thereof.

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In some cases, you can identify forward-looking statements by terms such as *may*, *will*, *should*, *could*, *would*, *expects*, *plans*, *anticipates*, *believes*, *estimates*, *projects*, *predicts*, *potential* and similar expressions intended to identify forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this offering circular to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial results include the cautionary statements set forth herein and in our filings with the Securities and Exchange Commission, including those set forth under *Risk Factors* set forth in Part II, Item 1A of this Quarterly Report as well as those described in our Annual Report on Form 10-K for the fiscal year ended September 24, 2011. We qualify all of our forward-looking statements by these cautionary statements.

## **OVERVIEW**

We are a developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to the healthcare needs of women. Our core business segments are focused on Breast Health, Diagnostics, GYN Surgical and Skeletal Health. On August 1, 2012, we completed our acquisition of Gen-Probe Incorporated ( *Gen-Probe* ) pursuant to the Agreement and Plan of Merger ( *Merger Agreement* ) entered into on April 29, 2012. Under the purchase method of accounting, we will allocate the total purchase price to the assets acquired and liabilities assumed from Gen-Probe based on their estimated fair values as of the date of the effective time of the acquisition, and the results of Gen-Probe will be included in our financial statements from and after the date of the acquisition.

Our Breast Health products include a broad portfolio of breast imaging and related products and accessories, including digital and film-based mammography systems, magnetic resonance imaging ( *MRI* ) breast coils, computer-aided detection ( *CAD* ) for mammography and MRI, minimally invasive breast biopsy devices, breast biopsy site markers, breast biopsy guidance systems, breast imaging comfort pads, and breast brachytherapy products. Our most advanced breast imaging platform, Dimensions, utilizes a new technology called tomosynthesis to produce three dimensional ( *3D* ) images, as well as conventional two dimensional ( *2D* ) full field digital mammography images. In the United States, our Dimensions product was approved in December 2008 by the FDA for providing conventional 2D images. On February 11, 2011, we received approval from the FDA to enable the 3D tomosynthesis capability of our Dimensions system. Our clinical results for the approval demonstrated that conventional 2D digital mammography with the addition of 3D tomosynthesis is superior to 2D digital mammography alone for both screening and diagnostics.

On November 27, 2011, we announced the commercial release of our C-View synthesized 2D image reconstruction algorithm that eliminates the need for a conventional 2D mammogram as a component of a 3D mammography exam. C-View software is approved for sale throughout the European Economic Area and in other countries recognizing the CE Mark. During the third quarter of fiscal 2012, we submitted a pre-market approval application to the FDA for this capability.

Our Diagnostics products include the ThinPrep System, which is primarily used in cytology applications such as cervical cancer screening, the Rapid Fetal Fibronectin Test, which assists physicians in assessing the risk of pre-term birth, and our molecular diagnostic reagents used for a variety of DNA and RNA analysis applications based on our proprietary Invader chemistry. Our current molecular diagnostic offerings based upon this Invader chemistry include Cervista HPV high risk ( *HR* ) and Cervista HPV 16/18 products to assist in the diagnosis of human papillomavirus ( *HPV* ), as well as other products to diagnose cystic fibrosis, cardiovascular risk and other diseases. On December 15, 2011, we announced the FDA approved our Cervista High Throughput Automation System ( *HTA* ) for use with our Cervista HPV HR test. The Cervista HTA system automates the DNA extraction and detection steps of the Cervista HPV HR test and allows for significantly less manual time during processing. This product was launched in January 2012. On August 1, 2012, our Diagnostics product offering was significantly expanded as a result of our acquisition of Gen-Probe.

Our GYN Surgical products include the NovaSure Endometrial Ablation System ( *NovaSure* ) and the MyoSure Hysteroscopic Tissue Removal System ( *MyoSure* ). The NovaSure system is a minimally invasive procedure for the treatment of heavy menstrual bleeding. The MyoSure system is a tissue removal device that is designed to provide incision-less removal of fibroids and polyps within the uterus. At the end of the second quarter of fiscal 2012, we decided to cease manufacturing, marketing and selling our Adiana Permanent Contraception System ( *Adiana* ) determining that the product was not financially viable and would not become so in the foreseeable future. On February 6, 2012, we received 510k clearance for our premarket application for the Aquilex fluid control system and started to commercialize Aquilex in the U.S. The Aquilex system is for hysteroscopic procedures and is designed to reduce procedure and anesthesia time while providing high quality visualization to the surgeon.



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Our Skeletal Health products include dual-energy X-ray bone densitometry systems, an ultrasound-based osteoporosis assessment product, and our Fluoroscan mini C-arm imaging products.

Unless the context otherwise requires, references to we, us, Hologic or our company refer to Hologic, Inc. and each of its consolidated subsidiaries.

### **Trademark Notice**

Hologic is a trademark of Hologic, Inc. Other trademarks, logos, and slogans registered or used by Hologic and its divisions and subsidiaries in the United States and other countries include, but are not limited to, the following:

Adiana, Affirm, ATEC, Aquilex, Celero, Cervista, C-View, Dimensions, Eviva, Fluoroscan, Healthcome, Interlace, Invader, LORAD, MammoPad, MammoSite, MultiCare, MyoSure, NovaSure, PreservCyt, QDR, Rapid iFN, Sahara, SecurView, Selenia, Sentinelle, Serenity, Suresound, StereoLoc, ThinPrep, THS, TCT, TLI IQ, and Trident.

### **RECENT DEVELOPMENTS**

On August 1, 2012, we completed our acquisition of Gen Probe. Such acquisition, and the significant indebtedness we incurred to fund that acquisition, subject us to risks and uncertainties as are described herein, including without limitation the risk factors set forth in Part II, Item 1A of this Quarterly Report.

Market acceptance of our medical products in the United States and other countries is dependent upon the purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patients' medical expenses by government healthcare programs, private insurers or other healthcare payors. In the United States, the Centers for Medicare & Medicaid Services, known as CMS, establish coverage and reimbursement policies for healthcare providers treating Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for our products and treatments. Coverage and reimbursement policies and rates applicable to patients with private insurance are dependent upon individual private payor decisions which may not follow the policies and rates established by CMS. The use of our products and treatments outside the United States is similarly affected by coverage and reimbursement policies adopted by foreign governments and private insurance carriers. CMS has not adopted a reimbursement rate for the use of 3D tomosynthesis, as tomosynthesis was only recently approved by the FDA in February 2011 in connection with our Premarket Approval ( PMA ) application for our Dimensions system. We are working with governmental authorities, healthcare providers, insurance companies and other third-party payors in our efforts to secure reimbursement for the use of 3D tomosynthesis. However, we cannot assure that these efforts will be successful. Failure to obtain, or delays in obtaining, adequate reimbursement for the use of 3D tomosynthesis would adversely affect sales of our Dimensions 3D systems.

The continuing uncertainty surrounding worldwide financial markets and macroeconomic conditions has caused and may continue to cause the purchasers of medical equipment to decrease or delay their medical equipment purchasing and procurement activities. Additionally, volatility in world credit markets have caused and continue to cause our customers to experience difficulty securing the financing necessary to purchase our products. Economic uncertainty and unemployment have and may continue to result in cost-conscious consumers focusing on acute care rather than wellness, which has and may continue to adversely affect demand for our products and procedures. Furthermore, governments and other third party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could adversely affect sales of our products. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

In March 2010, significant reforms to the healthcare system were adopted as law in the United States. The law includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and imposes new and/or increased taxes. Specifically, the law requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on United States sales of certain medical devices beginning in 2013. We expect that our products will fall under the government classification requiring the excise tax. Product sales in the United States represented 72% and 76% of our worldwide net product sales for the nine months ended June 23, 2012 and the year ended September 24, 2011, respectively.

We operate in a highly regulated industry and other governmental actions may adversely affect our business, operations or financial condition, including, without limitation: new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery and payment for health care products and services; changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval



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of new products and result in lost market opportunity; changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products and treatments; new laws, regulations and judicial decisions affecting pricing or marketing practices; and changes in the tax laws relating to our operations, including those associated with the recently adopted healthcare reform law discussed above.

Professional societies, government agencies, practice management groups, private health/science foundations, and organizations involved in healthcare issues may publish guidelines, recommendations or studies to the healthcare and patient communities from time to time. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, cost-effectiveness, and use of related preventative services and treatments/therapies. Recommendations, guidelines or studies that are followed by patients and healthcare providers could result in decreased use of our products. A number of healthcare-related organizations and agencies have issued or proposed contrasting recommendations, and some of these current recommendations could significantly reduce the amount of screening using our ThinPrep, Cervista HPV, Selenia, Dimensions and related products and adversely affect the sale of those products. For example, in March, 2012, the U.S. Preventative Services Task Force, known as USPSTF, and the American Cancer Society released updates in which they have recommended less frequent cervical cancer screening, similar to the guidelines released by the American Congress of Obstetrics and Gynecologists, known as ACOG, in November, 2009. However, the USPSTF recommendations now also include HPV co-testing for certain patient populations, an update from their draft guidelines in October 2011.

Over the last few years, there have been periodic significant fluctuations in foreign currencies relative to the U.S. dollar. The ongoing fluctuations of the value of the U.S. dollar, including the recent strengthening of the U.S. dollar against the Euro, may cause our products to be less competitive in international markets and may impact sales and profitability over time. Historically, a majority of our capital equipment sales to international dealers were denominated in U.S. dollars. However, more sales are now denominated in the Euro compared to the U.S. dollar for our Euro zone dealers. In addition, we have international sales, principally in our Diagnostics segment, that are denominated in foreign currencies. The value of these sales is also impacted by fluctuations in the value of the U.S. dollar. Given the uncertainty in the worldwide financial markets, foreign currency fluctuations may be significant in the future, and if the U.S. dollar continues to strengthen, we may experience a material adverse effect on our international revenues and operating results.

**ACQUISITIONS****Gen-Probe Incorporated**

On August 1, 2012, we completed our acquisition of Gen-Probe pursuant to the Merger Agreement entered into on April 29, 2012. Under the terms and conditions of the Merger Agreement, at the effective time and as a result of the acquisition, each share of common stock of Gen-Probe issued and outstanding immediately prior to the effective time of the acquisition was cancelled and converted into the right to receive \$82.75 in cash. We estimate the purchase price to be approximately \$4.0 billion, which was funded through available cash and financing consisting of senior secured credit facilities and Senior Notes discussed below.

Concurrent with closing the Gen-Probe acquisition, on August 1, 2012, we and certain domestic subsidiaries entered into a credit and guaranty agreement (the "Credit Agreement") with Goldman Sachs Bank USA in its capacity as administrative and collateral agent, and the lenders party thereto (collectively, the "Lenders"). Pursuant to the terms and conditions of the Credit Agreement, the Lenders agreed to provide senior secured financing in an aggregate amount of up to \$2.8 billion. On August 1, 2012 concurrently with the closing of the Gen-Probe acquisition, we borrowed \$2.5 billion aggregate principal under the Credit Agreement. In addition, concurrent with closing the Gen-Probe acquisition, on August 1, 2012, we completed a private placement of \$1.0 billion aggregate principal amount of our 6.25% senior notes due August 1, 2020 ("Senior Notes") at an offering price of 100% of the aggregate principal amount of the Senior Notes.

Gen-Probe, headquartered in San Diego, California, is a leader in molecular diagnostics products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility.

**TCT International Co., Ltd.**

On June 1, 2011, we acquired TCT International Co., Ltd. ("TCT"), a privately-held distributor of medical products, including our ThinPrep Pap Test, related instruments and other diagnostic and surgical products. TCT's operating subsidiaries are located in Beijing, China. Our acquisition of TCT enabled us to obtain an established nationwide sales organization and customer support infrastructure in China as we execute on our strategy to expand internationally. The purchase price was \$148.4 million. In addition, the majority of the former shareholders of TCT may receive two annual contingent earn-out payments (subject to adjustment) not to exceed \$200.0 million less the deferred payment. Subsequent to the acquisition date, our results of operations include the results of TCT, which are primarily reported within our Diagnostics reporting segment

and to a lesser extent within our GYN Surgical reporting segment.



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The contingent earn-out payments are based on a multiple of incremental revenue growth for the one year periods beginning January 1, 2011 and January 1, 2012 as compared to the respective prior year periods, and are payable after the first and second anniversaries from the date of acquisition, respectively. Since these payments are contingent on future employment, they are being recognized as compensation expense ratably over the required service periods, the first and second year anniversaries from the date of acquisition. Based on actual and projected revenues for the TCT business, we recorded compensation expense of \$15.0 million and \$42.6 million for the three and nine month periods ended June 23, 2012, respectively, and \$2.0 million for the three and nine month periods ended June 25, 2011. As of June 23, 2012, we had accrued \$60.1 million for these contingent payments, and \$54.0 million was paid in the fourth quarter of fiscal 2012 for the first earn out period.

### **Interlace Medical, Inc.**

On January 6, 2011, we acquired Interlace Medical, Inc. ( Interlace ), a privately-held company located in Framingham, Massachusetts. Interlace is the developer, manufacturer and supplier of MyoSure. The purchase price was comprised of \$126.8 million in cash ( Initial Consideration ), which was net of certain adjustments, plus two annual contingent payments up to a maximum of an additional \$225.0 million in cash. Subsequent to the acquisition date, our results of operations include the results of Interlace, which has been integrated within our GYN Surgical reporting segment.

The contingent payments are based on a multiple of incremental revenue growth during a two-year period following the completion of the acquisition. Pursuant to ASC 805, *Business Combinations*, we recorded this liability at its estimated fair value based on future revenue projections of the Interlace business under various potential scenarios and weighted probability assumptions of these outcomes. As of the date of acquisition, these cash flow projections were discounted using a rate of 15.6%, based on the weighted-average cost of capital of the acquired business plus a credit risk premium for non-performance risk related to the liability pursuant to ASC 820. This analysis resulted in an initial contingent consideration liability of \$86.6 million, which is being adjusted periodically as a component of operating expenses based on changes in the fair value of the liability. During the second quarter of fiscal 2012, the first measurement period lapsed resulting in a total contingent consideration amount recorded for this period of \$51.8 million, which was disbursed to the former shareholders of Interlace net of amounts withheld for certain legal indemnification purposes. We recorded a benefit of \$10.8 million and a charge of \$37.8 million for the three and nine month periods ended June 23, 2012, respectively, and charges of \$3.3 million and \$6.0 million for the three and nine month periods ended June 25, 2011, respectively, for changes in the fair value of the contingent consideration liability. As of June 23, 2012, we had accrued \$78.9 million for the second measurement period contingent payment.

### **Beijing Healthcome Technology Company, Ltd.**

On July 19, 2011, we completed our acquisition of Beijing Healthcome Technology Company, Ltd. ( Healthcome ), a privately-held manufacturer of medical equipment, including mammography equipment, located in Beijing, China. Healthcome develops and manufactures analog mammography products targeted to lower tier hospital segments in China. Subsequent to acquisition, we worked to integrate our selenium detector technology into the Healthcome mammography system, and on December 21, 2011, we received SFDA approval in China for our Serenity digital mammography system. We began selling this product in China in the second quarter of fiscal 2012, and intend to commercialize it throughout Asia and potentially other emerging markets in the future.

The purchase price was \$9.8 million in cash, subject to adjustment. In addition, we are obligated to make future payments to the shareholders, who remain employed, up to an additional \$7.1 million over three years. Since these payments are contingent on future employment, they are being recognized as compensation expense ratably over the respective service periods. Based on the terms of the contingent consideration arrangements, we recorded compensation expense of \$0.5 million and \$1.5 million for the three and nine month periods ended June 23, 2012, respectively.

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All dollar amounts in tables are presented in thousands.

**Product Sales**

	June 23, 2012		Three Months Ended June 25, 2011		Change		June 23, 2012		Nine Months Ended June 25, 2011		Change	
	%		%				%		%			
	of		of				of		of			
	Total		Total				Total		Total			
	Amount	Revenue	Amount	Revenue	Amount	%	Amount	Revenue	Amount	Revenue	Amount	%
<i>Product Sales</i>												
Breast Health	\$ 135,375	29%	\$ 135,729	30%	\$ (354)	0%	\$ 424,529	30%	\$ 402,875	30%	\$ 21,654	5%
Diagnostics	156,476	33%	142,106	32%	14,370	10%	459,062	32%	417,227	32%	41,835	10%
GYN Surgical	77,316	16%	78,974	18%	(1,658)	(2)%	232,307	16%	225,468	17%	6,839	3%
Skeletal Health	15,426	3%	15,981	4%	(555)	(3)%	48,876	3%	46,775	4%	2,101	4%
	\$ 384,593	82%	\$ 372,790	83%	\$ 11,803	3%	\$ 1,164,774	82%	\$ 1,092,345	83%	\$ 72,429	7%

Breast Health product sales were flat in the current three month period compared to the corresponding period in the prior year. In the current three month period, our digital mammography systems revenue decreased \$2.8 million compared to the corresponding period in the prior year due to a decrease in the number of Selenia systems sold, primarily in the United States, a slight deterioration of average selling prices, and a continued shift in Selenia product mix and configuration differences. We have experienced the trend of selling more Selenia Performance models, which have fewer features than our base Selenia model and carry lower average selling prices than our full-featured Selenia models. In addition, we sold more Selenia systems internationally as a percentage of total Selenia systems, and average selling prices are lower in our international markets compared to the domestic market. Partially offsetting the Selenia decrease, we sold more units of our 2D and 3D Dimensions product, which have higher average selling prices than our Selenia models, in the current quarter compared to the corresponding period in the prior year. However, configuration differences in the Dimensions models resulted in lower average selling prices worldwide. Further, during the third quarter of fiscal 2012, our digital mammography systems revenues were impacted by an accelerated shift of orders from 2D mammography systems to our new 3D Dimensions tomosynthesis mammography systems, including orders that were placed but not shipped during the quarter. The customer readiness requirement for tomosynthesis is more extensive than the 2D systems, and therefore, the shift from 2D to 3D tomosynthesis mammography orders contributed to a delay in system installations in the third quarter of fiscal 2012. In addition, our breast biopsy products revenue increased \$2.8 million in the current quarter compared to the corresponding period in the prior year due to the increase in the number of Eviva and Celero biopsy devices sold in the United States, partially offset by a decline of ATEC devices sold worldwide.

In the current nine month period, Breast Health product revenues increased 5% compared to the corresponding period in the prior year primarily due to the increase in our breast biopsy products revenue of \$14.9 million as a result of an increase in the number of Eviva and Celero biopsy devices sold in the United States. In addition, our digital mammography systems revenue increased \$7.0 million in the current nine month period compared to the corresponding period in the prior year primarily attributable to an increase in the number of units sold of both of our 2D and 3D Dimensions products worldwide, partially offset by lower average selling prices in the current nine month period primarily due to configuration differences in the Dimensions models. Partially offsetting the increase in revenues from the Dimensions systems was a decrease in the number of Selenia systems sold, primarily in the United States, and to a lesser extent, Selenia product mix and configuration differences, consistent with the factors discussed above for the decrease in the current three month period. We expect the shift in sales from our Selenia products to our Dimensions products to continue.

Diagnostics product sales increased 10% in both the current three and nine month periods compared to the corresponding periods in the prior year primarily due to an increase of \$9.0 million and \$25.4 million in ThinPrep pap tests revenue in the current three and nine month periods, respectively. This increase was principally from an increase in the sales price of ThinPrep in China as well as higher volumes from the inclusion of revenues of TCT (our former distributor in that country acquired in the third quarter of fiscal 2011), and to a lesser extent, an increase in the number of ThinPrep pap tests sold in other international markets, partially offset by a decline in domestic units sold. We also experienced growth in our molecular diagnostics products, which contributed revenue increases of \$4.3 million and \$10.0 million in the current three and nine month periods, respectively, as we continue to gain new customer accounts and unit sales to existing customers increase. In addition, in the current nine month period, we sold more diagnostics instruments internationally, increasing revenue by \$3.0 million.

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GYN Surgical product sales decreased 2% in the current three month period compared to the corresponding period in the prior year primarily due to a decline in sales of NovaSure devices of \$5.7 million and the Adiana system of \$3.6 million, partially offset by an increase in MyoSure system sales of \$6.8 million. The MyoSure system was FDA approved shortly before we acquired Interlace in January 2011 and the product continues to gain strong market acceptance. We experienced a decrease in the number of NovaSure devices sold, primarily in the United States, which we primarily attribute to the continuing effect of unemployment and economic uncertainty, which has resulted in patients delaying surgery or opting for lower cost and generally less effective alternatives. The reduction in Adiana system revenues was due to our decision to cease manufacturing, marketing and selling the product as of the end of the second quarter of fiscal 2012, determining it was not financially viable and would not become so in the foreseeable future.

In the current nine month period, GYN surgical product sales increased 3% due to the inclusion of the Myosure system, which contributed an increase of \$21.1 million of revenue in the current nine month period, partially offset by a decrease in NovaSure devices revenue of \$11.2 million in the current nine month period compared to the corresponding period in the prior year. While we experienced an increase in the number of NovaSure devices sold internationally, these increases were more than offset by a decline in the number of NovaSure devices sold domestically, as described above, and lower average selling prices driven by product mix and more international sales. In addition, Adiana system revenues declined \$4.7 million in the current nine month period compared to the corresponding period in the prior year.

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Skeletal Health product sales decreased 3% in the current three month period compared to the corresponding periods in the prior year primarily due to a decline of \$1.1 million in osteoporosis assessment product sales domestically. Partially offsetting this decrease was an increase in mini C-arm sales of \$0.6 million primarily due to the introduction of our new Insight product. In the current nine month period Skeletal Health product sales increased 4% primarily due to an increase of \$2.0 million in osteoporosis assessment product sales internationally.

Product sales by geography as a percentage of total product sales were as follows:

	Three Months Ended		Nine Months Ended	
	June 23, 2012	June 25, 2011	June 23, 2012	June 25, 2011
United States	72%	75%	73%	76%
Europe	12%	15%	12%	14%
Asia	10%	6%	9%	6%
All others	6%	4%	6%	4%
	100%	100%	100%	100%

The increase in product sales in Asia as a percentage of total product sales was primarily attributable to increased sales resulting from our acquisition of TCT.

**Service and Other Revenues**

	Three Months Ended						Nine Months Ended					
	June 23, 2012		June 25, 2011		Change		June 23, 2012		June 25, 2011		Change	
	% of		% of				% of		% of			
	Total		Total				Total		Total			
	Amount	Revenue	Amount	Revenue	Amount	%	Amount	Revenue	Amount	Revenue	Amount	%
Service and Other Revenues	\$ 85,635	18%	\$ 78,292	17%	\$ 7,343	9%	\$ 249,330	18%	\$ 229,959	17%	\$ 19,371	8%

Service and other revenues are primarily comprised of revenue generated from our field service organization to provide ongoing service, installation and repair of our products. Service and other revenues increased 9% and 8% in the current three and nine month periods, respectively, compared to the corresponding periods in the prior year primarily in our Breast Health business due to an increase in the number of service contracts driven by an increase in our installed base of our digital mammography systems, which are no longer under warranty.

**Cost of Product Sales**

	Three Months Ended						Nine Months Ended					
	June 23, 2012		June 25, 2011		Change		June 23, 2012		June 25, 2011		Change	
	% of		% of				% of		% of			
	Product		Product				Product		Product			
	Amount	Revenue	Amount	Revenue	Amount	%	Amount	Revenue	Amount	Revenue	Amount	%
Cost of Product Sales	\$ 134,062	35%	\$ 129,141	35%	\$ 4,921	4%	\$ 420,429	36%	\$ 385,863	35%	\$ 34,566	9%
Cost of Product Sales Amortization of Intangible Assets	45,280	12%	44,877	12%	403	1%	135,792	12%	131,478	12%	4,314	3%
	\$ 179,342	47%	\$ 174,018	47%	\$ 5,324	3%	\$ 556,221	48%	\$ 517,341	47%	\$ 38,880	7%



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Product sales gross margin was flat at 53% in the current quarter compared to the corresponding period in the prior year, and decreased to 52% in the current nine month period compared to 53% in the corresponding period in the prior year.

**Cost of Product Sales.** The cost of product sales as a percentage of product sales was 35% and 36% in the current three and nine month periods, respectively, compared to 35% in both the corresponding periods in the prior year. Cost of product sales as a percentage of product revenues in the current three month period decreased in GYN Surgical, remained flat for Diagnostics and increased in Breast Health and Skeletal Health compared to the corresponding period in the prior year, resulting in a flat overall gross margin rate. In the current nine month period, cost of product sales as a percentage of product revenues increased in GYN Surgical, remained relatively flat in Breast Health and Skeletal Health and decreased in Diagnostics compared to the corresponding period in the prior year resulting in an overall lower gross margin rate in the current nine month period compared to the corresponding period in the prior year.

The GYN Surgical gross margin rate for the current three month period improved due to lower production and sales of the Adiana system, which had a much lower gross margin rate compared to GYN Surgical's other core products. On April 30, 2012, we announced that we were ceasing to manufacture, market and sell the Adiana system, determining that the product was not financially viable and would not become so in the foreseeable future. The shift in product sales to more MyoSure devices from the Adiana system has resulted in a higher gross margin, although this was partially offset by the decline in NovaSure device sales, which carry a higher gross margin. Included in cost of product sales in the current three month period were additional charges of \$1.5 million for changes in estimates related to the Adiana product line discontinuance charges. GYN Surgical's gross margin rate in the current nine month period was significantly impacted by our decision to shut-down the Adiana product line resulting in an aggregate charge of \$17.9 million in the second quarter of fiscal 2012 for the write-off of inventory, manufacturing equipment and equipment at customer sites, and contractual purchase orders for which there was no expected future use of the materials and components. In addition, lower sales of the NovaSure system resulted in a lower gross margin rate, which was partially offset by the mix shift to sales of our MyoSure system versus lower Adiana system sales. For additional information pertaining to the Adiana product line discontinuance charges, please refer to Note 14 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

Diagnostics' gross margin rate was relatively flat in the current quarter compared to the corresponding period in the prior year. Improved ThinPrep pap test margins, primarily attributable to higher volumes and higher average selling prices in China attributable to our TCT acquisition, were offset by reduced margins in our molecular diagnostics business, which experienced unfavorable product mix shift and selling price pressures. In the current nine month period, Diagnostics' gross margin rate improved compared to the corresponding period in the prior year primarily due to an increase in ThinPrep pap test volume resulting in lower fixed overhead costs per unit and favorable manufacturing variances. In addition, the increase in sales price in China attributable to our acquisition of TCT contributed to the improved gross margin.

Breast Health experienced a decrease in gross margin in the current three month period compared to the corresponding periods in the prior year primarily due to a decrease in the number of Selenia systems sold, primarily in the United States, a slight deterioration of average selling prices, and a continued shift in Selenia product mix and configuration differences. We sold more Selenia Performance models, which have fewer features than our base Selenia model and carry lower average selling prices than our full-featured Selenia models. In addition, we sold more Selenia systems internationally as a percentage of total Selenia systems, and average selling prices are lower in our international markets compared to the domestic market. We also experienced lower average selling prices for our Dimensions models discussed above. In addition, the sales mix within our breast biopsy products resulted in a lower gross margin rate as we sold more Eviva disposables and less ATEC disposables as a percentage of revenue compared to the corresponding period in the prior year. Eviva disposables carry a higher manufacturing cost and additional royalty charges. In the current nine month period, Breast Health's gross margin rate was relatively flat. The gross margin rate for our digital mammography systems increased due to higher sales of our 3D Dimensions systems, which have higher average selling prices and gross margins than our Selenia systems, and an increase in 3D tomosynthesis software upgrades. Partially offsetting the improvement was an increase in Selenia Performance systems sales as a percent of total Selenia system sales compared to the corresponding periods in the prior year. Our Selenia Performance systems have lower gross margins than our full-featured Selenia systems. We also sold more Selenia systems internationally as a percentage of total Selenia systems where average selling prices are lower compared to the domestic market. Also offsetting the overall increase in Breast Health's gross margin was the sales mix within our breast biopsy products as we sold more Eviva disposables and less ATEC disposables as a percentage of revenue compared to the corresponding period in the prior year.

Skeletal Health gross margin decreased in the current quarter due to a decline in osteoporosis assessment product sales and product mix compared to the corresponding period in the prior year. In the current nine month period, gross margin was flat.

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**Cost of Product Sales Amortization of Intangible Assets.** Amortization of intangible assets relates to acquired developed technology. These intangible assets are generally amortized over their estimated useful lives of between 8.5 and 20 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed. The economic pattern is based on undiscounted future cash flows. The increase in amortization expense in the current three and nine month periods compared to the corresponding periods in the prior year is primarily due to the inclusion of additional amortization expense related to the technology assets acquired from our Interlace acquisition in the second quarter of fiscal 2011. In addition, there was an increase in amortization expense due to the method of recognition based on the expected economic benefits of the underlying assets, primarily related to the intangible assets acquired in the Cytac merger in the first quarter of fiscal 2008.

**Cost of Service and Other Revenues**

	June 23, 2012		Three Months Ended June 25, 2011		Change		June 23, 2012		Nine Months Ended June 25, 2011		Change	
	% of		% of				% of		% of			
	Amount	Service	Amount	Service	Amount	%	Amount	Service	Amount	Service	Amount	%
<i>Cost of Service and Other Revenue</i>	\$ 46,246	54%	\$ 42,503	54%	\$ 3,743	9%	\$ 137,763	55%	\$ 124,981	54%	\$ 12,782	10%

Service and other revenues gross margin was 46% and 45% in the current three and nine month periods, respectively, compared to 46% in both the corresponding periods in the prior year. Within our Breast Health segment, the continued conversion of a high percentage of our domestic installed base of digital mammography systems to service contracts upon expiration of the warranty period has resulted in higher gross margins, offset by increased costs in our Diagnostics segment for our higher installed base of ThinPrep processors and imagers. In the nine month period, gross margin decreased to 45% due to additional expenses incurred related to international expansion, which has resulted in the hiring of additional service personnel, increasing compensation and travel costs worldwide. In addition, service costs have increased in our Diagnostics segment due to an increase in our installed base of ThinPrep processors and imagers.

**Operating Expenses**

	June 23, 2012		Three Months Ended June 25, 2011		Change		June 23, 2012		Nine Months Ended June 25, 2011		Change	
	% of		% of				% of		% of			
	Amount	Total	Amount	Total	Amount	%	Amount	Total	Amount	Total	Amount	%
<i>Operating Expenses</i>												
Research and development	\$ 26,229	6%	\$ 29,325	7%	\$ (3,096)	(11)%	\$ 83,868	6%	\$ 87,817	7%	\$ (3,949)	(5)%
Selling and marketing	76,368	16%	72,981	16%	3,387	5%	232,367	16%	211,619	16%	20,748	10%
General and administrative	43,421	9%	39,755	9%	3,666	9%	131,319	9%	119,062	9%	12,257	10%
Amortization of intangible assets	15,733	3%	14,794	3%	939	6%	47,204	3%	43,842	3%	3,362	8%
Contingent consideration compensation expense	15,502	3%	3,161	0%	12,341	390%	44,064	3%	4,216	0%	39,848	945%
Contingent consideration fair value adjustments	(13,276)	(3)%	629	0%	(13,905)	(2,211)%	35,034	2%	(3,546)	0%	38,580	(1,088)%
Gain on sale of intellectual property, net						0%	(12,424)	(1)%	(84,502)	(6)%	72,078	(85)%
Litigation-settlement charges						0%	440	0%	450	0%	(10)	(2)%
	136	0%			136	100%	828	0%		%	828	100%

Restructuring and  
divestiture charges

\$ 164,113	35%	\$ 160,645	36%	\$ 3,468	2%	\$ 562,700	40%	\$ 378,958	29%	\$ 183,742	48%
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**Research and Development Expenses.** Research and development expenses decreased in the current three and nine month periods compared to the corresponding periods in the prior year. The reduction of expenses compared to the prior year for both periods was primarily attributable to a decrease in compensation and benefits due to lower bonus expenses, and a reduction in clinical trials and regulatory costs, which was primarily driven by the status and timing of projects. Research and development primarily reflects spending on new product development programs, regulatory compliance and clinical research and trials. At any point in time, we have a number of different research projects and clinical trials being conducted and the timing of these projects and related costs can vary period to period.



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**Selling and Marketing Expenses.** Selling and marketing expenses increased 5% and 10% in the current three and nine month periods, respectively, compared to the corresponding periods in the prior year. These increases were primarily due to additional expenses from the inclusion of TCT, an increase in the number of sales personnel in the GYN Surgical business segment, an increase in compensation and benefits for annual salary increases and higher commissions, continuing product launch activities related to our 3D Dimensions product, and higher travel expenses. The increase in both periods was partially offset by lower expenditures for our direct-to-consumer advertising campaign for NovaSure. The inclusion of Interlace in the current nine month period also contributed to higher expenses compared to the corresponding period in the prior year.

**General and Administrative Expenses.** General and administrative expenses increased 9% and 10% in the current three and nine month periods, respectively, compared to the corresponding periods in the prior year primarily due additional expenses from the inclusion of TCT, higher acquisition-related transaction costs associated with the proposed Gen-Probe acquisition and consulting services. In the current three month period, these increases were partially offset by lower legal fees, lower compensation and benefits due to lower bonus expenses and a reduction in the Nonqualified Deferred Compensation Plan liability, which is driven by the underlying market changes of hypothetical investments, and a decrease in depreciation expense. In addition, in the prior year corresponding quarter, we recorded charges for an ongoing sales tax audit and no amounts were recorded in the current quarter. In the current nine month period, expenses were higher compared to the corresponding period in the prior year primarily due to an increase in bad debt expense internationally, charges for an ongoing state sales tax audit, and invoice collection fees from higher credit card payments, partially offset by an overall decrease in compensation and benefits due to lower bonus expense and lower stock compensation expense as higher valued restricted stock units fully vested in fiscal 2011 and lower depreciation expense.

**Amortization of Intangible Assets.** Amortization of intangible assets results from customer relationships, trade names, business licenses and non-compete agreements related to our acquisitions. These intangible assets are generally amortized over their estimated useful lives of between 2 and 30 years using a straight-line method or, if reliably determinable, based on the pattern in which the economic benefits of the assets are expected to be consumed utilizing expected undiscounted future cash flows. The increase in the current three and nine months compared to the corresponding periods in the prior year is due to the addition of intangible assets from the Interlace and TCT acquisitions, and an increase in amortization due to the method of recognition based on the expected economic benefits of the underlying assets, primarily related to the intangible assets acquired in the Cytac merger in fiscal 2008.

**Contingent Consideration Compensation Expense.** In connection with our recent acquisitions, we are obligated to make contingent earn-out payments. Amounts recorded in this financial statement line item are those contingent payments that are contingent on future employment. These payments are also generally based on achieving certain performance milestones, typically incremental revenue growth, as is the case for TCT. The amounts recorded in fiscal 2012 primarily relate to TCT and, to a lesser extent, Healthcome. Amounts recorded in fiscal 2011 primarily relate to TCT and Interlace. For additional information, please refer to Note 3 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

**Contingent Consideration Fair Value Adjustments.** In connection with our acquisitions of Sentinelle Medical and Interlace, we may be required to pay future consideration that is contingent on achieving certain revenue based milestones. As of each respective acquisition date, we recorded contingent consideration liabilities for the estimated fair value of the amount we expect to pay to the former shareholders of the acquired business. This liability is not contingent on future employment and is based on future revenue projections of the respective businesses under various potential scenarios and weighted probability assumptions of these outcomes. At each reporting period, we re-measure the fair value of these liabilities and record the changes in fair value through a separate line item within our Consolidated Statements of Income. Increases or decreases in the fair value of contingent consideration liabilities can result from accretion of the liability for the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. As a result of changes in our estimates from the second quarter of fiscal 2012, we recorded a benefit of \$13.3 million in the current quarter due to lower revenue estimates for both Interlace and Sentinelle Medical, resulting in a decrease in the fair value of the respective contingent consideration liabilities of \$10.8 million and \$2.5 million, respectively. In the current nine month periods, we recorded a net charge of \$35.0 million reflecting an increase in the fair value of the Interlace liability due to higher revenue estimates, partially offset by the Sentinelle Medical benefit. In the three month period in the prior year, we recorded a net charge of \$0.6 million reflecting a net increase in the fair values of these liabilities comprised of a charge of \$3.3 million for accretion of the Interlace liability partially offset by a reduction in the fair value of the Sentinelle Medical liability of \$2.7 million due primarily to changes in revenue assumptions. In the nine month period in the prior year, we recorded a net benefit of \$3.5 million comprised of a reduction of \$9.6 million of the Sentinelle Medical liability primarily for changes in revenue assumptions, partially offset by charges of \$6.0 million related to Interlace for accretion of the liability. For additional explanation of the accounting for this liability, please refer to Note 3 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

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**Gain on Sale of Intellectual Property, Net.** During the second quarter of fiscal 2012, we received a scheduled payment of \$12.5 million from K-V Pharmaceutical Company ( K-V ) pursuant to our amended agreement, which was recorded net of amounts owed to the original inventor of Makena. During the second quarter of fiscal 2011, we received FDA approval of Makena, and all rights to Makena were transferred to K-V. Upon transfer, we received \$12.5 million, and including the \$79.5 million received in prior periods, we recorded a gain on the sale of intellectual property, net of the write-off of certain assets, of \$84.5 million in the second quarter of fiscal 2011. For additional information, please refer to Note 7 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

**Restructuring and Divestiture Charges.** In connection with our decision to cease manufacturing and selling our Adiana system discussed above, we incurred additional net charges of \$0.2 million in the third quarter of fiscal 2012 in addition to charges of \$0.4 million recorded in the second quarter of fiscal 2012 comprised of severance and other contractual obligations. In addition, we abandoned certain lease space in the second quarter of fiscal 2012 resulting in charges of \$0.4 million. For additional information pertaining to restructuring and divestiture charges, please refer to Note 14 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

**Interest Income**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
<b>Interest Income</b>	\$ 695	\$ 485	\$ 210	43%	\$ 1,947	\$ 1,352	\$ 595	44%

Interest income increased in the current three and nine month periods compared to the corresponding period in the prior year primarily due to an increase in cash and cash equivalents.

**Interest Expense**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
<b>Interest Expense</b>	\$ (25,593)	\$ (28,673)	\$ 3,080	(11)%	\$ (83,614)	\$ (85,767)	\$ 2,153	(3)%

Interest expense consists primarily of the interest costs and the related amortization of the debt discount of our convertible notes as well as the amortization of deferred financing costs. The decrease in interest expense in the current three and nine month periods compared to the corresponding periods in the prior year were primarily due to a decrease in the amortization of the debt discount as a result of the convertible note exchanges discussed below. Based on applying the effective interest rate method to amortize the debt discount on the convertible notes, amortization expense increases annually until maturity. The convertible note exchanges result in re-establishing the discount and related amortization schedule and hence a reduction in amortization expense in the first year.

**Loss on Debt Extinguishment**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
<b>Loss on Debt Extinguishment</b>	\$	\$	\$	%	\$ (42,347)	\$ (29,891)	\$ (12,456)	42%

In the second quarter of fiscal 2012, pursuant to separate, privately-negotiated exchange agreements, we retired \$500.0 million in aggregate principal of our 2.00% Convertible Senior Notes due 2037 ( 2007 Notes ) for \$500.0 million in aggregate principal of new 2.00% Convertible Notes due 2042 ( 2012 Notes ). This exchange enabled us to extend the first put date out approximately four and a quarter years to March 1, 2018 as well as the subsequent put dates as disclosed in the Liquidity and Capital Resources section of this Management's Discussion and Analysis. In consideration, the equity

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conversion price of the notes was reduced to approximately \$31.18 from \$38.59, and we must pay the cash coupon for four and a quarter more years, consistent with extending the first put date, instead of accreting the coupon to the principal as required under the original terms. In connection with this transaction, we recorded a loss on debt extinguishment of \$42.3 million, which includes the write-off of the pro-rata allocation of deferred financing costs.

In the first quarter of fiscal 2011, pursuant to separate, privately-negotiated exchange agreements, we retired \$450.0 million in aggregate principal of our 2007 Notes for \$450.0 million in aggregate principal of new 2.00% Convertible Exchange Senior Notes due 2037 ( 2010 Notes ). This exchange enabled us to extend the first put date out three years to December 15, 2016 from December 13, 2013 as well as the subsequent put dates as disclosed in the Liquidity and Capital Resources section of this Management's Discussion and Analysis. In consideration, the equity conversion price of the notes was reduced to \$23.03 from \$38.59, and we must pay the cash coupon for three more years, consistent with extending the first put date, instead of accreting the coupon to the principal as required under the original terms. In connection with this transaction, we recorded a loss on debt extinguishment of \$29.9 million, which includes the write-off of the pro-rata allocation of deferred financing costs.

**Other (Expense) Income, net**

	Three Months Ended				Nine Months Ended			
	June 23, 2012	June 25, 2011	Change		June 23, 2012	June 25, 2011	Change	
	Amount	Amount	Amount	%	Amount	Amount	Amount	%
<i>Other (Expense) Income, net</i>	\$ (622)	\$ (1,304)	\$ 682	(52)%	\$ 2,897	\$ (938)	\$ 3,835	(409)%

In the third quarter of fiscal 2012, this account was primarily comprised of losses on the cash surrender value of life insurance contracts related to our Nonqualified Deferred Compensation Plan, which is driven by underlying changes in stock market valuations, of \$1.1 million, partially offset by other miscellaneous gains of \$0.5 million. For the current nine month period, this account was primarily comprised of gains on the cash surrender value of life insurance contracts related to our Nonqualified Deferred Compensation Plan of \$1.9 million, other miscellaneous gains of \$0.5 million, and net foreign currency transaction gains of \$0.4 million.

In the third quarter of fiscal 2011, this account was primarily comprised of losses on cash surrender value of life insurance contracts related to our Nonqualified Deferred Compensation Plan of \$0.5 million, net foreign currency transaction losses of \$0.5 million, and an impairment charge of \$0.3 million on a cost-method investment. For the prior year nine month period, this account was primarily comprised of impairment charges of \$2.4 million on cost-method investments and net foreign currency transaction losses of \$0.5 million, partially offset by gains on cash surrender value of life insurance contracts related to our Nonqualified Deferred Compensation Plan of \$1.8 million.

**Provision for Income Taxes**

	Three Months Ended				Nine Months Ended			
	June 23, 2012	June 25, 2011	Change		June 23, 2012	June 25, 2011	Change	
	Amount	Amount	Amount	%	Amount	Amount	Amount	%
<i>Provision for Income Taxes</i>	\$ 31,413	\$ 8,228	\$ 23,185	282%	\$ 32,170	\$ 56,199	\$ (24,029)	(43)%

Our effective tax rates for the three and nine month periods ended June 23, 2012 were 57.1% and 88.6%, respectively, compared to 18.5% and 30.3%, respectively, for the corresponding periods in the prior year. For the three and nine months ended June 23, 2012, the effective tax rates were higher than the statutory rate primarily due to non-deductible contingent consideration compensation expense related to TCT, fair value adjustments related to the Interlace and Sentinelle Medical contingent consideration liabilities, and state taxes. The Company also established a \$2.6 million valuation allowance for Canadian tax credits due to uncertainties surrounding its ability to generate future taxable income to fully utilize these tax assets. For the three months ended June 25, 2011, the effective tax rate was less than the statutory rate primarily due to reversing \$8.2 million in income tax reserves due to settling the United States Internal Revenue Service (the IRS) federal audit for fiscal years 2007, 2008 and 2009 and the statute of limitations expiring in various federal, state and foreign jurisdictions, and the Section 199 manufacturing deduction. For the nine months ended June 25, 2011, the effective tax rate was less than the statutory rate primarily due to the Section 199 manufacturing deduction, reversal of income tax reserves, current year U.S. and Canadian research credits, the retroactively reinstated Federal research credit, and the tax benefit generated from the debt extinguishment loss recorded in the first quarter of fiscal 2011.

**Table of Contents****Segment Results of Operations**

We report our business as four segments: Breast Health, Diagnostics, GYN Surgical and Skeletal Health. The accounting policies of the segments are the same as those described in the notes to the consolidated financial statements included in our 2011 Annual Report on Form 10-K. We measure segment performance based on total revenues and operating income. The discussion that follows is a summary analysis of total revenues and the primary changes in operating income by segment.

**Breast Health**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
Total Revenues	\$ 211,460	\$ 205,185	\$ 6,275	3%	\$ 645,443	\$ 606,403	\$ 39,040	6%
Operating Income	\$ 48,910	\$ 47,230	\$ 1,680	4%	\$ 145,196	\$ 132,365	\$ 12,831	10%
Operating Income as a % of Segment Revenue	23%	23%			22%	22%		

Breast Health revenues increased in the current quarter compared to the corresponding period in the prior year primarily due to the \$6.6 million increase in service revenues that was substantially related to additional service contracts for the increased number of digital mammography systems in our installed base, partially offset by the reduction in product revenue discussed above. The increase in revenue in the current nine month compared to the corresponding period in the prior year was due to the increase in product revenue of \$21.7 million discussed above and \$17.4 million increase in service revenues.

Operating income for this business segment increased in the current three and nine month periods compared to the corresponding periods in the prior year primarily due to an increase in gross margin on an absolute dollar basis as a result of increased revenues discussed above. Operating expenses in the current quarter were relatively flat with the corresponding period in the prior year and increased in the current nine month period compared to the corresponding prior year period.

In the current quarter, while absolute gross margin dollars increased, the overall gross margin rate decreased to 48.9% compared to 49.6% in the corresponding period in the prior year due primarily to the decline in product gross margin discussed above. The product gross margin rate decreased to 48.1% in the current quarter compared to 49.8% in the corresponding period in the prior year. Operating expenses remained consistent in the current quarter compared to the corresponding prior year period and included net benefits of \$2.5 million and \$2.7 million, respectively, to adjust the Sentinelle Medical contingent consideration liability to fair value.

In the current nine month period, the overall gross margin rate increased to 49.2% from 48.8% in the corresponding period in the prior year due primarily to improvements in product gross margin discussed above. The product gross margin rate increased to 49.6% in the current quarter compared to 48.7% in the corresponding period in the prior year. Partially offsetting the increase in gross margin, operating expenses were higher in the current nine month period compared to the corresponding period in the prior year primarily due to the net benefit of \$9.6 million recorded in the prior year compared to \$2.7 million in the current year period to adjust the Sentinelle Medical contingent consideration liability to fair value and contingent compensation expense of \$1.5 million related to Healthcome in the current nine month period. In addition, expenses were higher in the current year period due to higher compensation costs related to hiring additional personnel, continuing product launch activities related to our 3D Dimensions product, medical education, travel, and litigation settlements and related expenses, partially offset by lower clinical trial expenses and lower distributor commissions.

**Diagnostics**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
Total Revenues	\$ 158,710	\$ 143,446	\$ 15,264	11%	\$ 464,615	\$ 420,777	\$ 43,838	10%

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Operating Income	\$ 11,466	\$ 24,052	\$ (12,586)	(52)%	\$ 53,223	\$ 157,149	\$ (103,926)	(66)%
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Operating Income as a % of Segment Revenue	7%	17%			11%	37%		
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Diagnostics revenues increased in the current three and nine month periods compared to the corresponding periods in the prior year primarily due to the increase in product sales discussed above.

Operating income for this business segment decreased in the current quarter compared to the corresponding period in the prior year. While gross margin in absolute dollars increased in the current quarter due primarily to the inclusion of TCT as discussed above, operating expenses more than offset the gross margin impact. Gross margin rate improved to 55.7% from 53.6%. Operating expenses increased due to the inclusion of TCT, which included an increase in contingent consideration compensation expense of \$12.9 million, acquisition transaction costs of \$3.4 million related to the Gen-Probe pending transaction, higher compensation, travel and trade shows, partially offset by lower spending on research projects and clinical trials based on the timing of projects.

Operating income for this business segment decreased in the current nine month period compared to the corresponding period in the prior year primarily due to the net gain of \$84.5 million on the sale of Makena intellectual property to KV in the second quarter of fiscal 2011 compared to a net gain of \$12.4 million recorded in the second quarter of fiscal 2012 for a scheduled payment received under the amended agreement. The balance of the decrease in the current nine month period of \$31.8 million was due to higher operating expenses partially offset by an increase in gross margin in absolute dollars. Gross margin rates improved to 56.1% in the current nine month period compared to 53.4% in the corresponding periods in the prior year as discussed above. Operating expenses increased in the current nine month period primarily due to the inclusion of TCT, which included an increase in contingent consideration compensation expense of \$40.4 million, acquisition transaction costs of \$3.4 million related to the Gen-Probe pending transaction, trade shows, higher compensation costs related to hiring additional personnel and annual salary increases, higher travel, and bad debt charges, primarily related to an international customer. These increases were partially offset by lower clinical trial and regulatory compliance costs based on the timing of projects.

**GYN Surgical**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
Total Revenues	\$ 77,672	\$ 79,353	\$ (1,681)	(2)%	\$ 233,395	\$ 226,526	\$ 6,869	3%
Operating Income (Loss)	\$ 17,740	\$ (483)	\$ 18,223	(3,773)%	\$ (50,650)	\$ 2,660	\$ (53,310)	(2,004)%
Operating Income (Loss) as a % of Segment Revenue	23%	(1)%			(22)%	1%		

GYN Surgical revenues decreased in the current three month period and increased in the current nine month period compared to the corresponding periods in the prior year due to the decrease and increase in product sales, respectively, discussed above.

Operating income for this business segment increased in the current quarter compared to the corresponding period in the prior year. While gross margin in absolute dollars decreased in the current quarter due primarily to additional charges of \$1.5 million related to the Adiana product line discontinuance discussed above, higher intangible asset amortization expense of \$1.6 million and lower product revenues, operating expenses decreased compared to the prior year quarter. The gross margin rate declined to 56.3% from 57.8%. Operating expenses declined in the current quarter primarily due to the benefit of \$10.8 million to adjust the Interlace contingent consideration liability to fair value compared to charges of \$4.3 million for contingent consideration in the prior year period, and a reduction in advertising expenditures for our NovaSure system's direct-to-consumer advertising campaign. In addition, operating expenses declined due to lower legal expenses, lower marketing and medical education expenses due to the discontinuance of the Adiana product line, and in the prior year period charges were recorded for an ongoing sales tax audit, partially offset by higher sales expenses for compensation and benefits for additional sales personnel, annual salary increases and commissions, and higher travel.

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This business segment incurred an operating loss in the current nine month period compared to income in the corresponding period in the prior year primarily attributable to the inclusion of Interlace's operations (acquired in the second quarter of fiscal 2011), which included a charge of \$37.8 million in the current nine month period to adjust the contingent consideration liability to fair value compared to aggregate contingent consideration charges of \$8.1 million in the prior year period, and the aggregate charge of \$20.0 million related to the Adiana product line discontinuance discussed above. Overall, gross margin in absolute dollars decreased in the current nine month period compared to the corresponding period in the prior year primarily due to the Adiana product line charge recorded in cost of product sales of \$19.5 million, and higher intangible asset amortization expense of \$7.7 million, partially offset by the impact of higher sales as discussed above. This resulted in the segment's gross margin rate declining to 47.4% from 57.4% in the corresponding period in the prior year.

In addition, this segment incurred higher operating expenses in the current nine month period compared to the corresponding period in the prior year primarily in sales and marketing related to higher compensation and benefits for additional sales personnel, annual salary increases and commissions, and higher travel, partially offset by a reduction in advertising expenditures for our NovaSure system's direct-to-consumer advertising campaign and lower marketing and medical education expenses related to the discontinuance of the Adiana product line. Operating expenses also increased due to additional expenditures of ongoing research and development projects and charges related to an ongoing state sales tax audit.

**Skeletal Health**

	Three Months Ended				Nine Months Ended			
	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%	June 23, 2012 Amount	June 25, 2011 Amount	Change Amount	%
Total Revenues	\$ 22,386	\$ 23,098	\$ (712)	(3)%	\$ 70,651	\$ 68,598	\$ 2,053	3%
Operating Income	\$ 2,411	\$ 3,117	\$ (706)	(23)%	\$ 9,651	\$ 8,850	\$ 801	9%
Operating Income as a % of Segment Revenue	11%	13%			14%	13%		

Skeletal Health revenues decreased in the current three month period and increased in the current nine month period compared to the corresponding periods in the prior year primarily due to the decrease and increase in product sales, respectively, discussed above.

Operating income decreased in the current three month period compared to the corresponding period in the prior year primarily due to the decline in sales, which reduced gross margin in absolute dollars. The gross margin rate declined to 41.5% from 43.3% in the corresponding period in the prior year. Operating expenses remained relatively flat.

Operating income increased in the current nine month period compared to the corresponding period in the prior year primarily due to the increase in revenues and improvement in gross margin rates to 44.1% from 43.1% in the corresponding period in the prior year. The improvement in gross margin dollars was partially offset by an increase in operating expenses primarily due to higher compensation and benefits and travel expenses.

**LIQUIDITY AND CAPITAL RESOURCES**

At June 23, 2012, we had \$977.9 million of working capital, and our cash and cash equivalents totaled \$905.1 million. Our cash and cash equivalents balance increased by \$192.8 million during the first nine months of fiscal 2012 due to cash generated from our operations and net proceeds from stock option exercises partially offset by cash used in investing and financing activities primarily for the payment of contingent consideration, capital expenditures and placement of equipment under customer usage agreements.

In the first nine months of fiscal 2012, our operating activities provided us with \$284.6 million of cash, which included net income of \$4.1 million, non-cash charges for depreciation and amortization aggregating \$231.1 million, non-cash interest expense of \$54.9 million related to our convertible notes, a loss on debt extinguishment of \$42.3 million, \$35.0 million of fair value adjustments for our contingent consideration liabilities related to recent acquisitions, stock-based compensation expense of \$26.4 million, and non-cash charges of \$16.4 million related to our decision to discontinue selling our Adiana





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product. These adjustments to net income were partially offset by a decrease in net deferred tax liabilities of \$124.3 million, primarily the result of recapturing taxes from the debt extinguishment and amortization of intangible assets. Cash provided by operations included a net cash inflow of \$14.0 million from changes in our operating assets and liabilities. Changes in our operating assets and liabilities were driven primarily by an increase in accrued expenses of \$40.2 million, principally from an increase in accrued compensation and benefits, and income tax accruals, partially offset by the semi-annual interest payment on our convertible notes. In addition, deferred revenue increased \$11.2 million as we continue convert our increasing installed base of digital mammography systems to service contract upon expiration of the warranty period. Offsetting these cash inflows is an increase in accounts receivable of \$22.1 million due to a higher level of sales to international customers, who typically have longer payment terms compared to domestic customers and a slight extension of our days sales outstanding, an increase in inventory of \$9.0 million primarily due to an increase in components on hand to support higher sales volume, the introduction of new products and last-time buys, and a decrease in accounts payable of \$8.2 million based on the timing of payments.

In the first nine months of fiscal 2012, we used \$51.9 million of cash for investing activities. This use of cash was primarily for purchases of property and equipment of \$53.4 million, which consisted primarily of the placement of equipment under customer usage agreements and manufacturing equipment and computer hardware, and the payment of contingent consideration to the former shareholders of Adiana of \$8.8 million. Partially offsetting these uses of cash was the receipt of \$12.5 million for a scheduled payment under our amended agreement in which we sold the rights to our Makena intellectual property to KV.

In the first nine months of fiscal 2012, our financing activities resulted in the use of cash of \$39.8 million, primarily for payments of contingent consideration of \$51.7 million related to our Interlace and Sentinelle acquisitions, debt issuance costs aggregating \$7.9 million related to our 2012 Notes and amounts incurred in the third quarter of fiscal 2012 related to the debt financing to fund the Gen-Probe acquisition, and \$5.7 million for employee-related taxes withheld for the net share settlement of vested restricted stock units. Under ASC 805, the payment of contingent consideration recorded at fair value in purchase accounting as of the acquisition date is treated as a financing activity. Partially offsetting these uses of cash were proceeds of \$21.7 million from the exercise of stock options.

**Acquisition of Gen-Probe Incorporated and Debt Financing**

On August 1, 2012, we completed the acquisition of Gen-Probe pursuant to the Merger Agreement entered into on April 29, 2012. Under the terms and conditions of the Merger Agreement, at the effective time and as a result of the acquisition, each share of common stock of Gen-Probe issued and outstanding immediately prior to the effective time of the acquisition was cancelled and converted into the right to receive \$82.75 in cash. We estimate the purchase price to be approximately \$4.0 billion, which was funded through available cash and financing consisting of senior secured credit facilities and the Senior Notes discussed below.

Gen-Probe, headquartered in San Diego, California, is a leader in molecular diagnostics products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility.

Concurrent with closing the Gen-Probe acquisition, on August 1, 2012, we and certain domestic subsidiaries (the **Guarantors**) entered into a credit and guaranty agreement (the **Credit Agreement**) with Goldman Sachs Bank USA, in its capacity as administrative and collateral agent, and the lenders party thereto (collectively, the **Lenders**). Pursuant to the terms and conditions of the Credit Agreement, the Lenders have committed to provide senior secured financing in an aggregate amount of up to \$2.8 billion. On August 1, 2012 concurrently with the closing of the Gen-Probe acquisition, we borrowed \$2.5 billion aggregate principal under the Credit Agreement.

The Guarantors have guaranteed our obligations under the credit facilities, and the credit facilities are secured by first-priority liens on, and a first-priority security interest in, substantially all of our assets and the assets of the Guarantors, including all of the capital stock of substantially all of the U.S. subsidiaries owned by us and the Guarantors, 65% of the capital stock of certain of our first-tier foreign subsidiaries and all intercompany debt. The security interests are evidenced by a pledge and security agreement by and among Goldman Sachs Bank USA, as collateral agent, us and the Guarantors and other related agreements, including certain intellectual property security agreements and mortgages.

The credit facilities under the Credit Agreement consist of:

\$1.0 billion senior secured tranche A term loan, ( **Term Loan A** ) with a final maturity date of August 1, 2017;

\$1.5 billion secured tranche B term loan ( **Term Loan B** ) with a final maturity date of August 1, 2019; and

\$300.0 million secured revolving credit facility ( Revolving Facility ) with a final maturity date of August 1, 2017. We are required to make scheduled principal payments under Term Loan A in increasing amounts ranging from \$12.5 million per three month period beginning October 31, 2012 to \$50.0 million per three month period commencing October 31,

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2015, and under Term Loan B in equal installments of \$3.75 million per three month period beginning on October 31, 2012 and for 27 three month periods thereafter. The remaining balance for each term loan is due at the maturity. Any amounts outstanding under the Revolving Facility are due at maturity. We are required to make principal repayments first, pro rata among the term loan facilities, and second to the Revolving Facility from specified excess cash flows from operations and from the net proceeds of specified types of asset sales, debt issuances, insurance recoveries and equity offerings. Subject to certain limitations, we may voluntarily prepay any of the credit facilities without premium or penalty.

All amounts outstanding under the Credit Agreement will bear interest, at our option, initially, with respect to all loans made under Term Loan A and the Revolving Facility: (i) at the Base Rate plus 2.00% per annum, or (ii) at the Adjusted Eurodollar Rate (i.e., the Libor rate) plus 3.00%, and with respect to loans made under Term Loan B: (i) at the Base Rate, with a floor of 2.00%, plus 2.50%, or (ii) at the Adjusted Eurodollar Rate, with a floor of 1.00% plus 3.50%. The applicable margin to the Base Rate or Eurodollar Rate on Term Loan A and the Revolving Facility are subject to specified changes depending on the total net leverage ratio as defined in the Credit Agreement. We are required to pay a quarterly commitment fee at an annual rate of 0.50% on the undrawn committed amount available under the Revolving Facility (which rate is subject to reduction depending on the total net leverage ratio as defined in the Credit Agreement).

The Credit Agreement contains affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants restricting the ability of the Company and the guarantors, subject to negotiated exceptions, to: incur additional indebtedness and additional liens on their assets, engage in mergers or acquisitions or dispose of assets, enter into sale-leaseback transactions, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. The credit facilities contain total net leverage ratio and interest coverage ratio financial covenants measured as of the last day of each fiscal quarter, as defined in the Credit Agreement.

The loan documents contain customary representations and warranties by us and the Guarantors, as well as customary events of default, including an event of default upon a change of control of the Company. An event of default will occur under the credit facilities if we, or in some circumstances one of the Guarantors, subject to the applicable cure periods, fail to make any payment when due under the loan documents, fail to comply with affirmative or negative covenants, make a misrepresentation, default on other specified indebtedness, become subject to specified events of bankruptcy, fail to discharge specified judgments or orders of dissolution, or become subject to specified claims under ERISA. If an event of default occurs and is not cured within any applicable grace period or is not waived, the Lenders have the right to accelerate repayment of the indebtedness under the credit facilities to the extent provided in the loan documents and applicable law, and upon certain events of default concerning bankruptcy such acceleration shall occur automatically. If our indebtedness evidenced by the credit facilities were accelerated, we and the Guarantors may not have sufficient funds to pay such indebtedness. In that event the Lenders would be entitled to enforce their security interests in the collateral securing such indebtedness, which will include substantially all of our assets and those of the Guarantors.

On August 1, 2012, we completed a private placement of \$1.0 billion aggregate principal amount of our Senior Notes at an offering price of 100% of the aggregate principal amount of the Senior Notes. The Senior Notes were not registered under the Securities Act or any state securities laws, and were offered only to qualified institutional buyers in reliance on Rule 144A under the Securities Act and outside the United States in accordance with Regulation S under the Securities Act. The Senior Notes are our general senior unsecured obligations and are guaranteed on a senior unsecured basis by the Guarantors.

On August 1, 2012, we, together with the Guarantors, entered into an indenture with Wells Fargo Bank, National Association, as trustee, relating to the Senior Notes. The Senior Notes mature on August 1, 2020 and bear interest at the rate of 6.25% per year, payable semi-annually on February 1 and August 1 of each year, commencing on February 1, 2013.

The indenture contains covenants which limit, among other things, our and certain of our subsidiaries' ability to incur additional indebtedness, pay dividends or repurchase or redeem capital stock, make certain investments, incur liens, enter into certain types of transactions with our affiliates, and sell assets or consolidate or merge with or into other companies. These covenants are subject to a number of exceptions and qualifications.

We may redeem up to 35% of the aggregate principal amount of the Senior Notes with the net cash proceeds of certain equity offerings at any time and from time to time before August 1, 2015, at a redemption price equal to 106.250% of the aggregate principal amount so redeemed, plus accrued and unpaid interest, if any, to the redemption date. We also have the option to redeem the Senior Notes on or after: August 1, 2015 through July 31, 2016 at 103.125% of par; August 1, 2016 through July 31, 2017 at 102.083% of par; August 1, 2017 through July 31, 2018 at 101.042% of par; and August 1, 2018 and thereafter at 100% of par. In addition, if we undergo a change of control, as provided in the indenture, we will be required to make an offer to purchase each holder's Senior Notes at a price equal to 101% of the aggregate principal amount of the Senior Notes, plus accrued and unpaid interest, if any, to the repurchase date.

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The indenture also contains certain customary events of default, including among others, failure to pay interest on the Senior Notes that continues for a period of 30 days after payment is due, failure to pay the principal of, or premium, if any, on the Senior Notes when due upon maturity, redemption, required repurchase, acceleration or otherwise, failure to comply with certain covenants and agreements after notice thereof, and certain events of bankruptcy or insolvency. An event of default under the indenture will allow the trustee or the holders of at least 25% in aggregate principal amount of the then-outstanding Senior Notes to declare to be immediately due and payable the principal amount of all such Senior Notes then outstanding, plus accrued but unpaid interest to the date of acceleration, or in the case of events of default involving bankruptcy or insolvency, such principal amount plus interest of all the Senior Notes shall become automatically due and payable immediately without any further action or notice.

On August 1, 2012, in connection with the issuance of the Senior Notes, we, together with the Guarantors, entered into an exchange and registration rights agreement with the initial purchasers of the Senior Notes. Pursuant to the terms of the registration rights agreement, we, together with the Guarantors, agreed to (i) file a registration statement covering an offer to exchange the Senior Notes for a new issue of identical exchange notes registered under the Securities Act on or before 180 days from August 1, 2012, (ii) use commercially reasonable efforts to cause such registration statement to become effective, and (iii) use commercially reasonable efforts to complete the exchange prior to 270 days after August 1, 2012. Under certain circumstances, we, together with the Guarantors, may be required to provide a shelf registration statement to cover resales of the Senior Notes.

### Convertible Notes

At June 23, 2012, our convertible notes, in the aggregate principal amount of \$1.725 billion, are recorded at \$1.54 billion, which is net of the unamortized debt discount attributed to the embedded conversion feature of the convertible notes. These notes consist of:

\$775 million of our 2.00% Convertible Senior Notes due 2037 issued in December 2007 (the 2007 Notes );

\$450 million of our 2.00% Convertible Exchange Senior Notes due 2037 issued in November 2010 (the 2010 Notes ); and

\$500 million of our 2.00% Convertible Senior Notes due 2042 issued in March 2012 (the 2012 Notes ).

The 2012 Notes were issued on March 5, 2012 pursuant to agreements entered into on February 29, 2012 in exchange for an equal principal amount of the 2007 Notes. In connection with the retirement of \$500 million principal of the 2007 Notes, we are required to recapture the original issuance discount we deducted for tax purposes and remit such amount aggregating \$59.0 million to the Internal Revenue Service in fiscal 2012. This amount had been recorded within the deferred tax liabilities and did not impact our results of operations.

Holders may require us to repurchase the 2007 Notes on December 13, 2013, and on each of December 15, 2017, 2022, 2027 and 2032, or upon a fundamental change, as provided in the indenture for the 2007 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest.

Holders may require us to repurchase the 2010 Notes on each of December 15, 2016, 2020, 2025, on December 13, 2030 and on December 14, 2035 or upon a fundamental change, as provided in the indenture for the 2010 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest.

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Holders may require us to repurchase the 2012 Notes on each of March 1, 2018, 2022, 2027 and 2032, and on March 2, 2037 or upon a fundamental change, as provided in the indenture for the 2012 Notes, at a repurchase price equal to 100% of their accreted principal amount, plus accrued and unpaid interest.

We may redeem any of the 2007 Notes, 2010 Notes and 2012 Notes beginning December 13, 2013, December 19, 2016, and March 6, 2018, respectively, by giving holders at least 30 days notice. We may redeem the 2007 Notes, 2010 Notes, and 2012 Notes either in whole or in part (i.e. in cash or a combination of cash and shares of our common stock) at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest, including contingent interest and liquidated damages, if any, to, but excluding, the redemption date.

For additional information on the terms of the convertible notes, see note 5 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

## **Contingent Earn-Out Payments**

In connection with our acquisitions, we have incurred the obligation to make contingent earn-out payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period. In certain circumstances, such as a change of control, a portion of these obligations may be accelerated. In addition, contractual provisions relating to these contingent earn-out obligations may include covenants to operate the businesses acquired in a manner that may not otherwise be most advantageous to us. These provisions may also result in the risk of litigation relating to the calculation of the amount due or our operation of the business acquired. Such litigation could be expensive and divert management attention and resources. Our obligation to make contingent payments may also result in significant operating expenses. Depending upon the particular facts and circumstances giving rise to the payment and our previous estimates, all or a portion of these payments may be required to be expensed by us when accrued. For example, our contingent earn-out obligations payable in connection with the TCT and Healthcome acquisitions will be fully expensed as accrued because our obligation to make these payments have been conditioned on the continued employment of certain key employees of TCT and Healthcome.

Our contingent consideration arrangements are recorded as either additional purchase price or compensation expense if continuing employment is required to receive such payments. Pursuant to ASC 805, contingent consideration that is deemed to be part of the purchase price is recorded as a liability based on the estimated fair value of the consideration we expect to pay to the former shareholders of the acquired business as of the acquisition date. This liability is re-measured each reporting period with the change in fair value recorded through a separate line item within our Consolidated Statements of Operations. Increases or decreases in the fair value of contingent consideration liabilities can result from accretion of the liability for the passage of time, changes in discount rates, and changes in the timing, probabilities and amount of revenue estimates. Contingent consideration arrangements from acquisitions completed prior to the adoption of ASC 805 (effective in fiscal 2010 for us) that are deemed to be part of the purchase price of the acquisition are not subject to the fair value measurement requirements of ASC 805 and are recorded as additional purchase price to goodwill.

In connection with the acquisition of Adiana, Inc., we have an obligation to the former Adiana shareholders to make contingent payments tied to the achievement of milestones. The contingent payments of up to \$155.0 million are based on worldwide sales of the Adiana system in the first year following FDA approval and on annual incremental sales growth thereafter through December 31, 2012. FDA approval of the Adiana system occurred on July 6, 2009, and we began accruing contingent consideration in the fourth quarter of fiscal 2009 based on the defined percentage of worldwide sales of the product. Since this contingent consideration obligation arose from an acquisition prior to the adoption of ASC 805, the amounts accrued are recorded as additional purchase price to goodwill. The purchase agreement includes an indemnification provision that provides for the reimbursement of qualifying legal expenses and liabilities associated with legal claims against the Adiana products and intellectual property, and we have the right to offset contingent consideration payments to the Adiana shareholders with these qualifying legal costs. We have been in litigation with Conceptus regarding certain intellectual property matters related to the Adiana product, and to the extent available, we have been recording legal fees incurred for this litigation matter (described in Note 6 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report) as a reduction to the accrued contingent consideration payments. We made payments of \$8.8 million and \$19.7 million in the first quarter of fiscal 2012 and 2011, respectively, to the former Adiana shareholders, net of amounts withheld for the legal indemnification provision. No contingent consideration has been earned and recorded through the first two quarters of fiscal 2012 as there has been no incremental revenue growth of the Adiana system in the current measurement period. On October 17, 2011, the jury returned a verdict in the Conceptus litigation matter in favor of Conceptus and awarded damages in the amount of \$18.8 million. On April 29, 2012, we entered into a license and settlement agreement with Conceptus in which Conceptus agreed to forgo the \$18.8 million jury award in consideration of us agreeing to a permanent injunction against the manufacture, sale and distribution of the Adiana product. At June 23, 2012, we have accrued \$18.8 million for the payment of contingent consideration to the former Adiana shareholders, which will be paid net of qualifying legal costs.



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We also have contingent consideration obligations related to our Sentinelle Medical, Interlace, TCT and Healthcome acquisitions. Pursuant to ASC 805, contingent consideration pertaining to Sentinelle Medical and Interlace is required to be recorded as a liability at fair value and the adjustments to fair value are recorded in the Consolidated Statement of Operations. Contingent consideration pertaining to TCT and Healthcome is contingent upon future employment and is being recorded as compensation expense as it is earned over the respective service periods. For additional information pertaining to the acquisitions, contingent consideration terms and the assumptions used to fair value contingent consideration, refer to note 3 and note 6 to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

In connection with our acquisition of Sentinelle Medical, we have an obligation to the former stockholders to make contingent payments over a two-year period of up to a maximum of \$250.0 million based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition. We made payments of \$4.1 million and \$4.3 million in the first quarter of fiscal 2012 and the third quarter of fiscal 2011, respectively. At June 23, 2012, this liability was recorded at \$4.0 million.

In connection with our acquisition of Interlace, we have an obligation to the former stockholders to make contingent payments over a two-year period up to a maximum payout of \$225.0 million based on a multiple of incremental revenue growth during the two-year period following the completion of the acquisition. During the second quarter of fiscal 2012, the first measurement period lapsed resulting in a total contingent amount recorded for this period of \$51.8 million, which was disbursed to the former shareholders of Interlace, net of amounts withheld for certain legal indemnification purposes. At June 23, 2012, this liability was recorded at \$78.9 million.

Under the sale and purchase agreement for TCT, \$35.0 million of the purchase price has been deferred for one year from the date of the acquisition. This amount plus a portion of the working capital adjustment of \$8.5 million were paid in the fourth quarter of fiscal 2012. An additional \$4.7 million working capital adjustment payment is due upon the completion of fiscal 2013. In addition, we have an obligation to certain of the former shareholders, based on future employment, to make contingent payments over a two year period not to exceed \$200.0 million less the Deferred Installment Payment. At June 23, 2012, we have accrued \$60.1 million for these contingent payments, and \$54.0 million was paid in the fourth quarter of fiscal 2012 for the first earn-out period.

In connection with our acquisition of Healthcome, we have an obligation to the former shareholders, who remain employed, to make contingent payments up to \$7.1 million over three years. At June 23, 2012, we have accrued \$1.8 million for these contingent payments.

## **Legal Contingencies**

We are currently involved in certain legal proceedings and claims. In connection with these legal proceedings and claims, management periodically reviews estimates of potential costs to be incurred by us in connection with the adjudication or settlement, if any, of these proceedings. These estimates are developed in consultation with outside counsel and are based on an analysis of potential litigation outcomes and settlement strategies. In accordance with ASC 450, *Contingencies*, loss contingencies are accrued if, in the opinion of management, an adverse outcome is probable and such outcome can be reasonably estimated. It is possible that future results for any particular quarter or annual period may be materially affected by changes in our assumptions or the effectiveness of our strategies relating to these proceedings. For additional information, please refer to Note 6(b) to the consolidated financial statements contained in Part I, Item 1 of this Quarterly Report.

## **Future Liquidity Considerations**

We believe that cash flow from operations will provide us with sufficient funds in order to fund our expected normal operations over the next twelve months. Our significant capital commitments include our obligations under our convertible notes and our potential obligation to pay contingent consideration in connection with certain of our recent acquisitions. In addition, as described above, on August 1, 2012, we incurred \$3.5 billion of additional indebtedness to fund our obligations to pay the merger consideration under our merger agreement with Gen-Probe. For risks relating to this additional indebtedness, see our risk factors under Part II, Item 1A.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The discussion and analysis of our financial condition and results of operations are based upon our interim consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported

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amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition for multiple element arrangements, allowance for doubtful accounts, reserves for excess and obsolete inventories, valuations, purchase price allocations and contingent consideration related to business combinations, expected future cash flows including growth rates, discount rates, terminal values and other assumptions used to evaluate the recoverability of long-lived assets and goodwill, estimated fair values of intangible assets and goodwill, amortization methods and periods, warranty reserves, certain accrued expenses, restructuring and other related charges, stock-based compensation, contingent liabilities, tax reserves and recoverability of our net deferred tax assets and related valuation allowance. We base our estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from these estimates if past experience or other assumptions do not turn out to be substantially accurate. Any differences may have a material impact on our financial condition and results of operations. For a discussion of how these and other factors may affect our business, see the *Cautionary Statement* and *Recent Developments* above and *Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended September 24, 2011, and *Risk Factors* set forth in Part II, Item 1A of this Quarterly Report as well as other cautionary statements set forth in this report.

The critical accounting estimates used in the preparation of our financial statements that we believe affect our more significant judgments and estimates used in the preparation of our consolidated financial statements presented in this report are described in Management's Discussion and Analysis of Financial Condition and Results of Operations and in the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended September 24, 2011. There have been no material changes to our critical accounting policies or estimates from those set forth in our Annual Report on Form 10-K.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

### *Disclosures about Offsetting Assets and Liabilities*

In December 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. ASU 2011-11 amended ASC 210, *Balance Sheet*, to converge the presentation of offsetting assets and liabilities between U.S. GAAP and IFRS. ASU 2011-11 requires that entities disclose both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. ASU 2011-11 is effective for fiscal years, and interim periods within those years, beginning after January 1, 2013, which is our fiscal year 2014. We are currently evaluating the impact of the adoption of ASU 2011-11 on our consolidated financial statements.

### *Presentation of Comprehensive Income*

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*, which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 does not change any of the components of comprehensive income, but it eliminates the option to present the components of other comprehensive income as part of the statement of stockholders equity. ASU 2011-05 is effective for us in our first quarter of fiscal 2013 and should be applied retrospectively. We are currently evaluating the impact of the adoption of ASU 2011-05 on our consolidated financial statements.

### *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements*

In May 2011, the FASB issued ASU No. 2011-04 *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 is effective for us in our second quarter of fiscal 2012 and should be applied prospectively. The adoption of ASU 2011-04 did not have a material impact on our consolidated financial statements.

### *Business Combinations*

In December 2010, the FASB issued ASU No. 2010-29, *Business Combinations (ASC Topic 805) Disclosure of Supplementary Pro Forma Information for Business Combinations*. ASU 2010-29 requires a public entity to disclose revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the prior year. It also requires a description of the nature and amount of material, nonrecurring adjustments directly attributable to the business combination included in the reported revenue and earnings. The new disclosure was effective for our first quarter of fiscal 2012 and did not have a material impact on our consolidated



financial statements.

**Table of Contents***Intangibles Goodwill and Other*

In December 2010, the FASB issued ASU No. 2010-28, *Intangibles Goodwill and Other (ASC Topic 350)*. ASU 2010-28 modifies Step 1 of the goodwill impairment test for reporting units with zero or negative carrying amounts. For those reporting units, an entity is required to perform Step 2 of the goodwill impairment test if it is more likely than not that a goodwill impairment exists. In determining whether it is more likely than not that a goodwill impairment exists, an entity should consider whether there are any adverse qualitative factors indicating that an impairment may exist. ASU 2010-28 is effective for us in fiscal 2012. We do not believe that ASU 2010-28 will have a material impact on our consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. ASU 2011-08 allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. ASU 2011-08 is effective for us beginning in fiscal 2013, although early adoption is permitted. We do not believe that ASU 2011-08 will have a material impact on our consolidated financial statements.

**Item 3. Quantitative and Qualitative Disclosure About Market Risk.**

*Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments.* Financial instruments consist of cash equivalents, accounts receivable, cost-method equity investments, insurance contracts and related Nonqualified Deferred Compensation Plan liability, accounts payable and debt obligations. Except for our outstanding convertible notes, the fair value of these financial instruments approximates their carrying amount. As of June 23, 2012, we have \$1.725 billion of principal of convertible notes outstanding, which are comprised of our 2007 Notes with a principal of \$775.0 million, our 2010 Notes with a principal of \$450.0 million, and our 2012 Notes with a principal of \$500.0 million. The convertible notes are recorded net of the unamortized discount on our consolidated balance sheets. The fair value of our 2007 Notes, 2010 Notes and 2012 Notes as of June 23, 2012 was approximately \$762.4 million, \$467.6 million and \$452.5 million, respectively.

*Primary Market Risk Exposures.* Our primary market risk exposure is in the areas of interest rate risk and foreign currency exchange rate risk. The return from cash and cash equivalents will vary as short-term interest rates change. A hypothetical 10% increase or decrease in interest rates, however, would not have a material adverse effect on our financial condition.

*Foreign Currency Exchange Risk.* Our international business is subject to risks, including, but not limited to: unique economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. Accordingly, our future results could be materially adversely impacted by changes in these or other factors.

We conduct business worldwide and maintain sales and service offices outside the United States as well as manufacturing facilities in Costa Rica, Germany, Canada and China. The expenses of our international offices are denominated in local currencies, except at our Costa Rica subsidiary, where the majority of the business is conducted in U.S. dollars. Our international sales are denominated in a number of currencies, primarily the Euro and U.S. dollar. Fluctuations in the foreign currency rates could affect our sales, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluations can result in a loss if we hold deposits of that currency.

We believe that the operating expenses of our international subsidiaries that are incurred in local currencies will not have a material adverse effect on our business, results of operations or financial condition. Our operating results and certain assets and liabilities that are denominated in the Euro are affected by changes in the relative strength of the U.S. dollar against the Euro. Our expenses, denominated in Euros, are positively affected when the U.S. dollar strengthens against the Euro and adversely affected when the U.S. dollar weakens. However, we believe that the foreign currency exchange risk is not significant. A hypothetical 10% increase or decrease in foreign currencies that we transact in would not have a material adverse impact on our financial condition or results of operations.

**Item 4. Controls and Procedures.**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the



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SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of June 23, 2012, 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. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

## **PART II OTHER INFORMATION**

### **HOLOGIC, INC.**

#### **Item 1. Legal Proceedings.**

Through our third quarter ended June 23, 2012, there have been no material changes in Legal Proceedings as previously disclosed in our Annual Report on Form 10-K for our fiscal year ended September 24, 2011 except as discussed below. Except for litigation in which we were jointly involved with Gen-Probe, this litigation does not include litigation to which Gen-Probe is a party, as we did not acquire Gen-Probe until August 1, 2012. Such litigation, to the extent it may be material, will be disclosed in our Annual Report on Form 10-K for our fiscal year ending September 29, 2012.

On May 22, 2009, Conceptus, Inc. filed suit in the United States District Court for the Northern District of California seeking a declaration by the Court that our planned importation, use, sale or offer to sell of its forthcoming Adiana Permanent Contraception System would infringe five Conceptus patents. On July 9, 2009, Conceptus filed an amended complaint alleging infringement of the same five patents by the Adiana system. The complaint sought preliminary and permanent injunctive relief and unspecified monetary damages. In addition to the amended complaint, Conceptus also filed a motion for preliminary injunction seeking to preliminarily enjoin sales of the Adiana System based on alleged infringement of certain claims of three of the five patents. A hearing on Conceptus' preliminary injunction motion was held on November 4, 2009, and on November 6, 2009, the Court issued an order denying the motion. On January 19, 2010, upon stipulation of the parties, the Court dismissed all claims relating to three of the five asserted patents with prejudice. A Markman hearing on claim construction took place on March 10, 2010 and a ruling was issued on March 24, 2010. On April 12, 2010, in response to our counterclaims of unfair competition filed in October of 2009, the Court granted Conceptus leave to amend its counterclaims adding charges of unfair competition. On June 23, 2010, upon stipulation of the parties, the judge dismissed the asserted claims of an additional patent leaving three claims of U.S. patent 7,506,650 being asserted against us in the case. On August 10, 2010, the parties entered into a settlement agreement dismissing all unfair competition claims against each other. A hearing on both parties' motions for summary judgment on the patent claims occurred on December 9, 2010, and on December 16, 2010, a ruling was issued granting us summary judgment of no infringement of one of the three asserted claims. A trial was held from October 3, 2011 through October 14, 2011 related to the asserted claims. On October 17, 2011 the jury returned a verdict in favor of Conceptus and awarded damages to Conceptus in the amount of \$18.8 million. Post trial motions were filed by both parties including a motion by Conceptus seeking to enjoin us from further sales of the Adiana system. A hearing on the post trial motions and injunction request took place on January 6, 2012, and on January 9, 2012, the judge issued an order denying Conceptus' motion for an injunction and further found that we will not be required to pay royalties on future sales of the Adiana system nor any supplemental damages. On January 19, 2012, the Court granted our motion to stay the payment of damages pending appeal. On February 8, 2012, we filed a notice of appeal to overturn the jury verdicts related to infringement and validity. On the same day Conceptus filed a notice of appeal to overturn the Court's denial of the permanent injunction. On April 29, 2012, we entered into a license and settlement agreement with Conceptus in which Conceptus agreed to forgo the \$18.8 million jury award in consideration of our agreeing to a permanent injunction against the manufacture, sale and distribution of the Adiana product. We also granted Conceptus a license to our intellectual property related to the Adiana product.

On June 9, 2010, Smith & Nephew, Inc. filed suit against Interlace, which we acquired on January 6, 2011, in the United States District Court for the District of Massachusetts. In the complaint, it is alleged that the Interlace MyoSure hysteroscopic tissue removal device infringes U.S. patent 7,226,459. The complaint seeks permanent injunctive relief and unspecified damages. A Markman hearing was held November 9, 2010, and a ruling was issued on April 21, 2011. On November 22, 2011, Smith & Nephew, Inc. filed suit against us in the United States District Court for the District of Massachusetts. In the complaint, it is alleged that use of the MyoSure hysteroscopic tissue removal system infringes U.S. patent 8,061,359. The complaint seeks preliminary and permanent injunctive relief and unspecified damages. On January 17,



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2012, at a hearing on Smith & Nephew's motion for preliminary injunction with respect to the suit filed November 22, 2011, the judge did not issue an injunction, consolidated the two matters for a single trial and scheduled a trial on the merits for both claims for June 25, 2012. A case management conference held on February 14, 2012 resulted in the trial being rescheduled to begin on August 20, 2012. On March 15, 2012, the Court heard summary judgment arguments related to the 459 patent and claim construction arguments related to the 359 patent. On June 5, 2012, the Court denied Smith & Nephew's request for summary judgment of infringement, denied Smith & Nephew's request for preliminary injunction, and denied our requests for summary judgment of non-infringement and invalidity. The trial remains scheduled for August 20, 2012. The purchase and sale agreement associated with the acquisition of Interlace includes an indemnification provision that provides for the reimbursement of a portion of legal expenses in defense of the Interlace intellectual property. We have the right to collect certain amounts set aside in escrow and, as applicable, offset contingent consideration payments of qualifying legal costs. We are recording legal fees incurred for this suit pursuant to the indemnification provision net within accrued expenses.

On February 10, 2012, C.R. Bard (as acquirer of SenoRx, Inc. SenoRx) filed suit against us in the United States District Court of Delaware. In the complaint, it is alleged that our MammoSite product infringes SenoRx's U.S. Patents 8,079,946 and 8,075,469. The complaint seeks permanent injunctive relief and unspecified damages.

On March 6, 2012, Enzo Life Sciences, Inc. (Enzo) filed suit against us in the United States District Court of Delaware. In the complaint, it is alleged that certain of our molecular diagnostics products, including without limitation products based on our proprietary Invader chemistry such as Cervista HPV high risk and Cervista HPV 16/18, infringe Enzo's U.S. Patent 6,992,180. The complaint seeks permanent injunctive relief and unspecified damages. We were formally served with the complaint on July 3, 2012, but no hearing has been scheduled.

A number of lawsuits have been filed against us, Gen-Probe Incorporated, and Gen-Probe's board of directors. These include: (1) Teamsters Local Union No. 727 Pension Fund v. Gen-Probe Incorporated, et al. (Superior Court of the State of California for the County of San Diego); (2) Timothy Coyne v. Gen-Probe Incorporated, et al. (Delaware Court of Chancery); and (3) Douglas R. Klein v. John W. Brown, et al. (Delaware Chancery Court). The two Delaware actions have been consolidated into a single action titled: In re: Gen-Probe Shareholders Litigation. The suits were filed after the announcement of the Gen-Probe Acquisition on April 30, 2012 as putative stockholder class actions. Each of the actions assert similar claims alleging that Gen-Probe's board of directors failed to discharge adequately its fiduciary duties to shareholders by failing to adequately value Gen-Probe's shares and ensure that Gen-Probe's shareholders received adequate consideration in our proposed acquisition of Gen-Probe, that the Gen-Probe Acquisition is the product of a flawed sales process, and that we aided and abetted the alleged breach of fiduciary duty. The plaintiffs demand, among other things, a preliminary and permanent injunction enjoining the Gen-Probe Acquisition and rescinding the transaction or any part thereof that has been implemented. On May 24, 2012, the plaintiffs in the Delaware action filed an amended complaint, adding allegations that the disclosures in Gen-Probe's preliminary proxy statement were inadequate. The defendants in the Delaware action answered the complaint on June 4, 2012. On July 18, 2012, the parties in the Delaware action entered into a memorandum of understanding regarding the settlement. The proposed settlement is conditioned upon, among other things, the execution of an appropriate stipulation of settlement, consummation of the merger, and final approval of the proposed settlement by the Delaware Court of Chancery. On May 21, 2012 and May 22, 2012, respectively, the defendants in the California action filed a motion to stay such action. On July 9, 2012, the plaintiffs in the California action filed voluntary dismissal without prejudice. On July 12, 2012, the California Superior Court entered an order dismissing the California complaint without prejudice.

### **Item 1A. Risk Factors**

*This report contains forward-looking information that involves risks and uncertainties, including statements regarding our plans, objectives, expectations and intentions. Such statements made in this report should be read as applicable to all forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed herein. Other risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect us. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this report. In these Risk Factors, unless otherwise indicated or the context otherwise requires, the words Hologic, we, us, our and ours refer to Hologic and its subsidiaries, including Gen-Probe and its subsidiaries.*

**Table of Contents****Risk Relating to our Business****The continuing worldwide macroeconomic uncertainty may adversely affect our business and prospects.**

Market acceptance of our medical products in the United States and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patients' medical expenses by government healthcare programs and third-party payors. The continuing uncertainty surrounding world financial markets and continuing weak worldwide macroeconomic conditions, including as a result of actual or potential debt default by certain European countries, have caused and may continue to cause the purchasers of medical equipment to decrease their medical equipment purchasing and procurement activities. Additionally, constrictions in world credit markets have caused and may continue to cause our customers to experience increased difficulty securing the financing necessary to purchase our products. Economic uncertainty as well as increasing health insurance premiums and co-payments may continue to result in cost-conscious consumers making fewer elective trips to their physicians and specialists, which in turn would adversely affect demand for our products and procedures. Furthermore, governments and other third party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could adversely affect sales of our products. If the current adverse macroeconomic conditions continue, our business and prospects may be negatively impacted.

**Sales and market acceptance of our products is dependent upon the coverage and reimbursement decisions made by third party payors. The failure of third party payors to provide appropriate levels of coverage and reimbursement for the use of our products and treatments facilitated by our products could harm our business and prospects.**

Sales and market acceptance of our medical products and the treatments facilitated by our products in the United States and other countries is dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. Market acceptance of our products and treatments has and will continue to depend upon our customers' ability to obtain an appropriate level of coverage for, and reimbursement from third-party payors for, these products and treatments. In the U.S., the Centers for Medicare & Medicaid Services, known as CMS, establish coverage and reimbursement policies for healthcare providers treating Medicare and Medicaid beneficiaries. Under current CMS policies, varying reimbursement levels have been established for our products and treatments. Coverage policies for Medicare patients may vary by regional Medicare carriers in the absence of a National Coverage Decision and reimbursement rates for treatments may vary based on the geographic price index. Coverage and reimbursement policies and rates applicable to patients with private insurance are dependent upon individual private payor decisions which may not follow the policies and rates established by CMS. The use of our products and treatments outside the United States is similarly affected by coverage and reimbursement policies adopted by foreign governments and private insurance carriers.

Significant reductions in reimbursement rates proposed or implemented for the use of any our products have had and may continue to have a material adverse effect on the sales of those products. On an annual basis, CMS publishes reimbursement rates for laboratory services, physician, hospital and ambulatory surgical center payments. CMS published proposed 2013 rates in July 2012. In 2012, the reimbursement rate for DXA in the freestanding center decreased by approximately 55%. The CMS reimbursement rates for 2012 also included a general reduction of 27% in the Sustainable Growth Rate (SGR) factor. This factor is used by CMS in a formula to determine doctor reimbursements and, if implemented, would correspondingly affect the reimbursement for the use of our products. This reduction did not go into effect in 2012 as a result of legislation passed by Congress but reductions for 2013 and future years will go into effect unless Congress takes further action.

Currently, there is not an established Current Procedural Terminology code, reimbursement rate or official coverage for the use of 3D tomosynthesis, as tomosynthesis was only recently approved by the FDA in February 2011 in connection with our PMA application for our Dimensions system. We are working with governmental authorities, professional societies, healthcare providers, insurance companies and other third-party payors in efforts to secure reimbursement for the use of 3D tomosynthesis. However, we cannot assure that these efforts will be successful. Failure to obtain, or delays in obtaining, adequate reimbursement for the use of 3D tomosynthesis would adversely affect sales of our Dimensions 3D systems.

**The adoption of healthcare reform in the United States and the uncertainty surrounding the implementation of these reforms could harm our business and prospects.**

The healthcare industry has undergone significant change driven by various efforts to reduce costs, trends toward managed care, cuts in Medicare, consolidation of healthcare distribution companies and collective purchasing arrangements by office-based healthcare practitioners. The effect of the implementation of the new U.S. health care reform law, adopted in March 2010, on our business is uncertain. Among other things, the law requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on U.S. sales of certain medical devices beginning January 1, 2013. We expect that this excise tax will apply to our products. U.S. net product sales will represent a substantial majority of our net revenues. Various healthcare reform proposals have also emerged at the state level. The new law and these proposals could reduce medical procedure volumes and impact the demand for our products or the prices at which we sell our products. In

addition, the excise tax will increase our costs of doing business. The impact of this law and these proposals could harm our



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business and prospects, results of operations and/or financial condition. Public debate of these issues will likely continue in the future. Healthcare reform proposals and medical cost containment measures in the United States and in many foreign countries could:

limit the use of our products and treatments;

reduce reimbursement available for such use;

further tax the sale or use of our products; or

adversely affect the use of new therapies for which our products may be targeted.

These reforms, cost containment measures and new taxes, including the uncertainty in the medical community regarding their nature and effect, could have an adverse effect on our customers' purchasing decisions regarding our products and treatments and could harm our business, result of operations, financial condition and prospects.

### **Changes in laws affecting the healthcare industry could adversely affect our revenues and profitability.**

We operate in a highly regulated industry. As a result, governmental actions may adversely affect our business, operations or financial condition, including:

new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery and payment for health care products and services;

changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and treatments and result in lost market opportunity;

changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products and treatments to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products or treatments, or otherwise adversely affect the market for our products and treatments; and

new laws, regulations and judicial decisions affecting pricing or marketing practices.

We anticipate that the government will continue to scrutinize our industry closely and that additional regulation by governmental authorities may increase compliance costs, exposure to litigation and other adverse effects to our operations.

### **Guidelines, recommendations and studies published by various organizations can reduce the use of our products.**

Professional societies, government agencies, practice management groups, private health/science foundations, and organizations involved in healthcare issues may publish guidelines, recommendations or studies to the healthcare and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, cost-effectiveness, and use of related therapies. Organizations like these have in the past made recommendations about our products and those of our competitors. Recommendations, guidelines or studies that are followed by healthcare providers and insurers could result in decreased use of our products. For example, in March, 2012, the U.S. Preventative Services Task Force, known as the USPSTF, and the American Cancer Society released updates in which they have recommended less frequent cervical cancer screening, similar to the guidelines released by the American Congress of Obstetrics and Gynecologists, known as the ACOG, in November, 2009. However, the USPSTF recommendations now also include HPV co-testing for certain

patient populations, an update from their draft guidelines in October, 2011.

**Our long-term success will depend upon our ability to successfully develop and commercialize new products and treatments and enhance our existing products and treatments.**

We are expending significant resources on our continuing research and development programs which are designed to develop new products and treatments and to enhance and improve our existing products and treatments. The successful development of our products and product enhancements is subject to numerous risks, both known and unknown, including:

unanticipated delays in development, clinical trials or the FDA's approval or clearance process;

access to capital;

budget overruns;

third party intellectual property;

technical problems; and

other difficulties that could result in the abandonment or substantial change in the design, development and commercialization of these new products, including, for example, changes requested by the FDA in connection with pre-market approval applications for products or 510(k) clearance.

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Given the uncertainties inherent with product development, introduction, and enhancement our efforts may not be completed on a timely basis or within budget, if at all. Our failure to develop new products and product enhancements on a timely basis or within budget, if at all, could harm our business and prospects.

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

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

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

In June 2010, Gen-Probe also entered into a collaboration agreement with Pacific Biosciences regarding the research and development of instruments integrating Gen-Probe's sample preparation technologies and Pacific Biosciences' single-molecule deoxyribonucleic acid, or DNA, sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the term of the collaboration will end December 15, 2012.

If any of our current collaboration agreements are terminated, or if we are unable to renew those collaborations on acceptable terms, we may 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 Gen-Probe's agreements with Novartis, Siemens or Pacific Biosciences, a court or arbitrator may not rule in our favor and our rights or obligations under an agreement subject to a dispute may be adversely affected, which may have an adverse effect on our business or operating results.

**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 and quality requirements, our ability to sell our products will be harmed.**

The manufacture of many of our products is highly complex and requires precise high quality manufacturing that is difficult to achieve. We have in the past and may in the future experience difficulties in manufacturing our products on a timely basis and in sufficient quantities. These difficulties have primarily related to delays and difficulties associated with ramping up production of newly introduced products and may lead to increased delivery lead-times and increased costs of manufacturing these products. In addition, production of these newer products may require the development of new manufacturing technologies and expertise, which we may be unable to develop. Our failure, including the failure of our contract manufacturers, to achieve and maintain the required high manufacturing standards could result in further delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals, increased warranty costs or other problems that could harm our business and prospects.

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.

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 the manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other regulatory agencies, and these facilities are subject to FDA requirements relating to the Quality System Regulation. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.



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### **Our business could be harmed if products contain undetected errors or defects or do not meet customer specifications.**

We are continuously developing new products and improving our existing products. Our existing and newly introduced products can contain undetected errors or defects. In addition, these products may not meet their performance specifications under all conditions or for all applications. If, despite internal testing and testing by customers, any of our products contain errors or defects or fail to meet customer specifications, then we may be required to enhance or improve those products or technologies. We may not be able to do so on a timely basis, if at all, and may only be able to do so at considerable expense. In addition, any significant reliability problems could result in adverse customer reaction, negative publicity, mandatory or voluntary recall or legal claims and could harm our business and prospects.

### **Our products may be subject to recalls even after receiving FDA clearance or approval, which could harm our business and prospects.**

The FDA and similar governmental bodies in other countries have the authority to require the recall of medical products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall could harm the reputation of our products and adversely affect our business and prospects. Gen-Probe has in the past voluntarily recalled products, which, in each case, required it to identify a problem and correct it. In May 2011, Gen-Probe voluntarily recalled certain Elucigene test kits for the detection of genetic mutations associated with cystic fibrosis because of issues it identified during quality control stability testing. All affected customers and appropriate regulatory authorities were advised of the voluntary recall and Gen-Probe has made a substitute product available. The affected product is CE marked, but is not cleared by the FDA and is not available for sale in the United States. In addition, in May 2011 Gen-Probe initiated a second voluntary recall of certain Elucigene branded tests in Canada upon determination that such products were not properly registered with Health Canada. In April 2012, Gen-Probe voluntarily recalled certain lots of LIFECODES PAK (platelet antibody) products after determining that the negative controls in the assays were increasing signals over time, leading to the potential for decreased product performance. All affected customers were advised of the voluntary recall and Gen-Probe made replacement products available. Gen-Probe classified this event as a Class III recall under the FDA's classification system.

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

### **Interruptions, delays, shutdowns or damage at our manufacturing facilities could harm our business.**

We and our contract manufacturers manufacture our products at a relatively limited number of different facilities located throughout the world. An interruption in manufacturing capabilities at any of these facilities, as a result of equipment failure or other reasons, could reduce, delay or prevent the production of our products. Our manufacturing facilities are subject to the risk of catastrophic loss due to unanticipated events, such as fires, earthquakes, explosions, floods or weather conditions. Our manufacturing facilities may experience plant shutdowns, strikes or other labor disruptions, or periods of reduced production as a result of equipment failures, loss of power, gray outs, delays in deliveries or extensive damage to any of our facilities, which could harm our business and prospects. Because some of our manufacturing operations are located outside the United States, including in Germany, Canada, Costa Rica, the United Kingdom and China, those manufacturing operations are also subject to additional challenges and risks associated with international operations described below.

### **Our delay or inability to obtain any necessary United States or foreign regulatory clearances or approvals for our newly developed products and treatments or product enhancements could harm our business and prospects.**

Our products and treatments are subject to a high level of regulatory oversight. Our delay or inability to obtain any necessary United States or foreign regulatory clearances or approvals for our newly developed products or product enhancements could harm our business and prospects. The process of obtaining clearances and approvals can be costly and time-consuming. In addition, there is a risk that any approvals or clearances, once obtained, may be withdrawn or modified.

Medical devices cannot be marketed in the United States without 510(k) clearance or premarket approval by the FDA. Any modifications to a device that has received a pre-market approval that affect its safety or effectiveness require a pre-market approval supplement or possibly a separate pre-market approval, either of which is likely to be time-consuming, expensive and uncertain to obtain. If the FDA requires us to seek one or more pre-market approval supplements or new pre-market approvals for any modification to a previously approved device, we may be required to cease marketing or to recall the modified device until we obtain approval, and we may be subject to significant criminal and/or civic sanctions, including but not limited to, regulatory fines or penalties.

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Medical devices sold in the United States must also be manufactured in compliance with FDA Good Manufacturing Practices, which regulate the design, manufacture, packing, storage and installation of medical devices. Moreover, medical devices are required to comply with FDA regulations relating to investigational research and labeling. States may also regulate the manufacture, sale and use of medical devices, particularly those that employ x-ray technology. Our products are also subject to approval and regulation by foreign regulatory and safety agencies.

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Delays in receipt of, or failure to obtain, clearances or approvals for future products could delay or preclude realization of product revenues from new products or result in substantial additional costs which could decrease our profitability. In August 2010, the FDA issued two reports outlining potential changes to the 510(k) regulatory process. In addition, in January 2011, the FDA issued an implementation plan containing 25 specific actions to be implemented in 2011 relating to the 510(k) regulatory process and associated administrative matters. The FDA also deferred action on several other initiatives, including the creation of a new class of devices that would be subject to heightened review processes, until the Institute of Medicine released a related report on the 510(k) regulatory process in July 2011. The FDA is reviewing the Institute of Medicine's report as well as public input to determine what, if any, recommendations the FDA will adopt with respect to the 510(k) regulatory process. Many of the actions proposed by the FDA could result in significant changes to the 510(k) regulatory process, which would likely complicate the process of obtaining clearance for products by the FDA.

### **The markets for our newly developed products and treatments and newly introduced enhancements to our existing products and treatments may not develop as expected.**

The successful commercialization of our newly developed products and treatments and newly introduced enhancements to our existing products and treatments are subject to numerous risks, both known and unknown, including:

uncertainty of the development of a market for such product or treatment;

trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than our products, technologies, treatments or therapies;

perceptions of our products or treatments as compared to other products and treatments;

recommendation and support for the use of our products or treatments by influential customers, such as hospitals, radiological practices, breast surgeons and radiation oncologists and treatment centers;

the availability and extent of data demonstrating the clinical efficacy of our products or treatments;

competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and

other technological developments.

Often, the development of a significant market for a product or treatment will depend upon the establishment of a reimbursement code or an advantageous reimbursement level for use of the product or treatment. Moreover, even if addressed, such reimbursement codes or levels frequently are not addressed until after a product or treatment is developed and commercially introduced, which can delay the successful commercialization of a product or treatment.

If we are unable to successfully commercialize and create a significant market for our newly developed products and treatments and newly introduced enhancements to our existing products and treatments our business and prospects could be harmed.

### **The markets for our Dimensions 3D tomosynthesis system may not develop as expected.**

The markets for our Dimensions 3D tomosynthesis system and related products may not continue to develop as expected. There is a significant installed base of conventional digital and screen-film mammography products in hospitals and radiological practices. The use of our Dimensions 3D tomosynthesis system in many cases would require these potential customers to either modify or replace their existing x-ray imaging equipment. As our Dimensions 3D tomosynthesis systems are generally more expensive than conventional mammography products, we believe

that a major factor in the market's acceptance of Dimensions 3D tomosynthesis systems has been and will continue to be based upon the benefits of tomosynthesis as compared to less expensive technologies. Moreover, as a new technology, there is currently limited, if any, reimbursement for the use of 3D tomosynthesis. We believe that our ability to continue to gain market acceptance of the Dimensions 3D tomosynthesis system and follow-on products depends on our ability to demonstrate the clinical efficacy and cost-effectiveness of the Dimensions 3D tomosynthesis system and to secure reimbursement to support the use of 3D tomosynthesis. We are seeking to work with healthcare providers, insurance companies and other third-party payors in connection with our efforts to promote, and to secure reimbursement for, the use of 3D tomosynthesis. However, we cannot assure that these efforts will be successful. The markets for our Dimensions 3D tomosynthesis system and related products have and will continue to be affected by published studies and reports relating to the comparative efficacy of tomosynthesis, as well as decisions relating to the reimbursement of healthcare providers for the use of the system. The publication of an adverse study, or an adverse decision relating to the reimbursement of the use of tomosynthesis, would likely significantly



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impair the adoption of this technology and harm our business. Sales of our Dimensions 3D tomosynthesis system may also be adversely affected by increased competition. Several companies, including Siemens, Giotto, Philips and Planmed, have recently introduced 3D tomosynthesis systems in certain foreign countries. We also are aware that other companies, several of which have substantially greater resources than we have, such as GE and Siemens, are developing 3D tomosynthesis systems for approval in the U.S. Because the markets for our Dimensions 3D tomosynthesis system and related products are relatively new, it is likely that our evaluation of the potential markets for these products will materially vary with time.

### **Our business may be harmed by the acquisition of Gen-Probe, our other prior acquisitions or acquisitions we may complete in the future.**

In addition to the acquisition of Gen-Probe, we have acquired a number of other businesses, technologies, product lines and products, and may make additional acquisitions in the future. Promising acquisitions are difficult to identify and complete for a number of reasons, including competition among prospective buyers and the need for regulatory, including antitrust, approvals. We may not be able to identify and successfully complete transactions. Any acquisition we may complete may be made at a substantial premium over the fair value of the net assets of the acquired company. Further, the long-term success of our acquisitions and any additional acquisitions we may complete in the future will depend upon our ability to realize the anticipated benefits from combining the acquired businesses with our business. We may fail to realize anticipated benefits for a number of reasons, including the following:

problems may arise with our ability to successfully integrate the acquired businesses, which may result in us not operating as effectively and efficiently as expected, and may include:

diversion of management time, as well as a shift of focus from operating the businesses to issues related to integration and administration or inadequate management resources available for integration activity and oversight;

failure to retain and motivate key employees;

failure to successfully oversee international sales efforts and inability to prevent FCPA violations;

failure to successfully obtain FDA approval or clearance for products under development;

failure to successfully obtain approval or clearance for products in foreign countries;

failure to successfully manage relationships with customers, distributors and suppliers;

failure of customers to accept new products;

failure to effectively coordinate sales and marketing efforts;

failure to combine product offerings and product lines quickly and effectively;

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failure to effectively enhance acquired technology and products or develop new products relating to the acquired businesses;

potential difficulties and inefficiencies in managing and operating businesses in multiple locations or operating businesses in which we have either limited or no direct experience;

potential difficulties integrating financial reporting systems;

potential difficulties in the timely filing of required reports with the SEC; and

potential difficulties in implementing controls, procedures and policies, including disclosure controls and procedures and internal controls over financial reporting, appropriate for a larger public company at companies that, prior to the acquisition of such companies, had lacked such controls, procedures and policies, which may result in ineffective disclosure controls and procedures or material weaknesses in internal controls over financial reporting;

we may not be able to achieve the expected synergies from an acquisition or it may take longer than expected to achieve those synergies;

an acquisition may result in future impairment charges related to diminished fair value of businesses acquired as compared to the price we paid for them;

an acquisition may involve restructuring operations or reductions in workforce which may result in substantial charges to our operations;

our current and prospective customers and suppliers may experience uncertainty associated with an acquisition, including with respect to current or future business relationships with us, the acquired business or the combined business and may attempt to negotiate changes in existing business;

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an acquisition may involve unexpected costs or liabilities, including as a result of pending and future Gen-Probe shareholder lawsuits relating to acquisitions or exercise by shareholders of their statutory appraisal rights, or the effects of purchase accounting may be different from our expectations;

an acquisition may involve significant deferred or contingent payments that may adversely affect our future liquidity or capital resources; and

the acquired businesses may be adversely affected by future legislative, regulatory, or tax decisions and/or changes as well as other economic, business and/or competitive factors.

Our failure to realize the anticipated benefits from combining acquired businesses could harm our business and prospects.

If we are successful in pursuing future acquisitions, we may be required to expend significant funds, incur additional debt or other obligations, or issue additional securities, which may negatively affect our operating results and financial condition. If we spend significant funds or incur additional debt or other obligations, our ability to obtain financing for working capital or other purposes could decline, and we may be more vulnerable to economic downturns and competitive pressures. We cannot guarantee that we will be able to finance additional acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

### **We will incur significant transaction and acquisition-related costs in connection with the acquisition of Gen-Probe.**

We expect to incur significant costs associated with our acquisition of Gen-Probe and combining the operations of the two companies. The substantial majority of the expenses resulting from the acquisition will be composed of transaction costs related to the acquisition, systems consolidation costs, and business integration and employment-related costs, including costs for severance, retention and other restructuring. We may also incur transaction fees and costs related to formulating integration plans. Additional unanticipated costs may be incurred in the integration of the two companies' businesses. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, should allow us to offset incremental transaction and acquisition-related costs over time, this net benefit may not be achieved in the near term, or at all.

### **Our business may be harmed by the contingent earnout obligations we incurred in connection with our acquisitions or acquisitions we may complete in the future.**

In connection with our acquisitions, we have incurred the obligation to make contingent earnout payments tied to performance criteria, principally revenue growth of the acquired businesses over a specified period. We also expect that acquisitions we may complete in the future may contain contingent earnout payments, and these payments could be significant. In certain circumstances, such as a change of control, a portion of these obligations may be accelerated. In addition, contractual provisions relating to these contingent earnout obligations may include covenants to operate the businesses acquired in a manner that may not otherwise be most advantageous to us. These provisions may also result in the risk of litigation relating to the calculation of the amount due or our operation of the business acquired. Such litigation could be expensive and divert management attention and resources. Our obligation to make contingent payments may also result in significant operating expenses. Depending upon the particular facts and circumstances giving rise to the payment and our previous estimates, all or a portion of these payments may be required to be expensed by us when accrued. For example, our contingent earnout obligations payable in connection with the TCT and Healthcome acquisitions will be fully expensed as accrued because our obligation to make these payments is conditioned on the continued employment of certain key employees of TCT and Healthcome. We cannot assure that we will have sufficient funds to pay our contingent obligations when due, or that such obligations, including the associated covenants relating to the operation of the acquired business, will not otherwise adversely affect our business, liquidity, capital resources or results of operations.

### **It may be difficult for us to implement our strategies for improving growth.**

Some of the markets in which we compete have been flat or declining over the past several years. To address this issue, we are pursuing a number of strategies to improve our growth, including:

expanding our product offerings;

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allocating research and development funding to products with higher growth prospects;

developing new applications for our technologies;

strengthening our presence in selected geographic markets;

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acquiring technologies and businesses that complement or augment our existing products and services;

implementing targeted customer initiatives; and

supporting cross-selling opportunities of products and services to take advantage of our breadth in product offerings.

We may not be able to successfully implement these strategies, and these strategies may not result in the growth of our business.

### **Consolidation in the healthcare industry could lead to increased demands for price concessions or the exclusion of some suppliers from certain of our significant market segments, which could harm our business and prospects.**

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry, including hospitals. This consolidation has resulted in greater pricing pressures, decreased average selling prices, and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may reduce competition and continue to exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations. In particular, we are dependent upon a relatively small number of large clinical laboratory customers in the United States for a significant portion of our sales of diagnostics products. Due in part to a trend toward consolidation of clinical laboratories in recent years and the relative size of the largest United States laboratories, it is likely that a significant portion of these sales will continue to be concentrated among a relatively small number of large clinical laboratories.

### **Our business is dependent on technologies we license, and if we fail to maintain these 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.**

Our business is dependent on licenses from third parties for some of our key technologies. For example, Gen-Probe's patented TMA technology is based on technology Gen-Probe has licensed from Stanford University. In addition, Gen-Probe has acquired exclusive worldwide diagnostic rights to the PCA3 gene from Diagnostics. We anticipate that we will 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 will provide us with exclusive rights to the subject technology or disease marker. If our license with respect to any of these technologies or markers is terminated for any reason, we may not be able to sell products that incorporate the technology. Similarly, we may lose competitive advantages if we fail to maintain exclusivity under an exclusive license.

Our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Our ability to design products that target these diseases may depend on our ability to obtain the necessary rights from the third parties that make any of these discoveries. In addition, there are a finite number of diseases and conditions for which Gen-Probe's 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 will require access to technologies and materials that may be subject to patents or other intellectual property rights held by third parties. We may need to obtain additional intellectual property rights in order to commercialize our products. We may be unable to obtain such rights on commercially reasonable terms or at all, which could adversely affect our ability to grow our business.

### **Our business could be harmed if we are unable to protect our proprietary technology.**

We have relied primarily on a combination of trade secrets, patents, and copyrights to protect our products and technology. Despite these precautions, unauthorized third parties may infringe our intellectual property, copy or reverse engineer portions of our technology. 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. We do not know if current or future patent applications will be issued with the scope of the claims sought, if at all, or whether any patents issued will be challenged or invalidated. The patents that we own or license could also be subject to interference proceedings or similar disputes over the priority of the inventions, and an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. 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.

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We have obtained or applied for corresponding patents and patent applications in several foreign countries for some of our patents and patent applications. There is a risk that these patent applications will not be granted or that the patent or patent application will not provide significant protection for our products and technology.

The rights provided by a patent are finite in time. Over the coming years, certain patents relating to current products will expire in the U.S. and abroad thus allowing third parties to utilize certain of our technologies.

Our competitors may independently develop similar technology that our patents do not cover. In addition, because patent applications in the United States are not generally publicly disclosed until eighteen months after the application is filed, applications may have been filed by third parties that relate to our technology. Moreover, there is a risk that foreign intellectual property laws will not protect our intellectual property rights to the same extent as intellectual property laws in the U.S. Even if we believed our proprietary information is protected by patents or otherwise, the initiation of actions to protect our proprietary information could be costly and divert the efforts and attention of our management and technical personnel, and the outcome of such litigation is often uncertain. As a result of these uncertainties, we could also elect to forego such litigation or settle such litigation without fully enforcing our proprietary rights. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or technology.

### **Our business could be harmed if we infringe upon the intellectual property rights of others.**

There has been substantial litigation regarding patent and other intellectual property rights in the medical device, diagnostic products and related industries. We have been involved in patent litigation, and may in the future be subject to claims of infringement of intellectual property rights possessed by third parties.

In connection with claims of patent infringement, we may seek to enter into settlement and/or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide to litigate such claims or to design around the patented technology. These actions could be costly and would divert the efforts and attention of our management and technical personnel. As a result, any infringement claims by third parties or claims for indemnification by customers resulting from infringement claims, whether or not proven to be true, may harm our business and prospects.

### **Our international operations and foreign acquisitions expose us to additional operational challenges that we might not otherwise face.**

We are subject to a number of additional risks and expenses due to our international operations, including our acquired businesses in China. Any of these risks or expenses could harm our operating results. These risks and expenses include:

difficulties in staffing and managing operations in multiple locations as a result of, among other things, distance, language and cultural differences;

protectionist laws and business practices that favor local companies;

difficulties in trade accounts receivable collection;

difficulties and expenses related to implementing internal controls over financial reporting and disclosure controls and procedures;

expenses associated with customizing products for clients in foreign countries;

possible adverse tax consequences;

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the inability to obtain favorable third-party reimbursements;

the inability to obtain required regulatory approvals;

governmental currency controls;

multiple, conflicting and changing government laws and regulations (including, among other things, antitrust and tax requirements, international trade regulations and the Foreign Corrupt Practices Act);

reduced protection for intellectual property rights in some countries;

political and economic changes and disruptions, export/import controls and tariff regulations;

the inability to effectively obtain or enforce intellectual property rights and otherwise protect against clone or knock off products; and

the lack of ability to enforce non-compete agreements with former owners of acquired businesses competing with us in China and other foreign countries.



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### **We utilize distributors for a portion of our sales, the loss of which could harm our revenues in the territory serviced by these distributors.**

We rely on strategic relationships with a number of key distributors for sales and service of our products. For example, Gen-Probe is dependent on Novartis to distribute the blood screening products it manufactures. Commercial blood screening product sales to Novartis accounted for 35% of Gen-Probe's total product sales for the first three months of 2012 and 35% of Gen-Probe's total product sales for 2011. In January 2009, Gen-Probe extended the term of its blood screening collaboration with Novartis to June 30, 2025, subject to earlier termination under certain limited circumstances specified in the collaboration agreement. If our relationship with Novartis or any of our other strategic relationships are terminated and not replaced, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected. If any of our distribution or marketing agreements are terminated, particularly Gen-Probe's collaboration agreement with Novartis, or if we elect to distribute new products directly, we will have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, general and administrative expenses. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to successfully market our products, our product sales will decrease. We may also be exposed to risks as a result of transitioning a territory from a distributor sales model to a direct sales model, such as difficulties maintaining relationships with specific customers, hiring appropriately trained personnel or ensuring compliance with local product registration requirements, any of which could result in lower revenues than previously received from the distributor in that territory.

### **Fluctuations in the exchange rates of European currencies and the other foreign currencies in which we conduct our business, in relation to the U.S. dollar, could harm our business and prospects.**

We maintain sales and service offices outside the United States, have manufacturing facilities in Germany, Costa Rica, Canada and China and conduct business worldwide. The expenses of our international offices are denominated in local currencies, except at our Costa Rica subsidiary, where the majority of business is conducted in U.S. dollars. Our foreign sales may be denominated in local currencies, the Euro or U.S. dollar. Historically, a majority of our sales of capital equipment to international dealers have been denominated in U.S. dollars; however in the second half of fiscal 2010 we began to invoice more of our European sales in the Euro.

Fluctuations in foreign currency exchange rates could affect our revenues, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluation can result in a loss if we hold deposits of that currency. In the last few years we have not hedged foreign currency exposures, but we may in the future hedge foreign currency denominated sales. There is a risk that any hedging activities will not be successful in mitigating our foreign exchange risk exposure and may adversely impact our financial condition and results of operations.

### **We rely on one or only a limited number of suppliers for some key components or subassemblies for our products. This reliance could harm our business and prospects.**

We rely on one or only a limited number of suppliers for some key raw materials, components or subassemblies for our products. Obtaining alternative sources of supply of these components could involve significant delays and other costs and regulatory challenges, and may not be available to us on reasonable terms, if at all. The failure of a component supplier or contract assembler to provide sufficient quantities, acceptable quality and timely components or assembly service at an acceptable price, or an interruption of supplies from such a supplier could harm our business and prospects. Any disruption of supplies of key components could delay or reduce shipments, which could result in lost or deferred sales.

Gen-Probe's current supplier of certain key raw materials for its amplified NAT assays, pursuant to a fixed-price contract, is Roche Molecular Biochemicals. Gen-Probe has a supply and purchase agreement for oligonucleotides for HPV with Roche Molecular Systems. Each of these entities is an affiliate of Roche Diagnostics GmbH, which is one of our primary competitors in molecular diagnostics.

### **We have only one third-party manufacturer for each of our molecular diagnostics 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 molecular diagnostics instrument product lines. KMC Systems, Inc., or KMC Systems, is the only manufacturer of the TIGRIS instrument; Stratec Biomedical Systems AG, or Stratec, is the only manufacturer of the PANTHER instrument; and Tecan Group Ltd., or Tecan, is the only manufacturer of the Cervista High Throughput Automation System. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with production delays, delivery schedules, manufacturing capability, quality control, quality assurance and costs.



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

We may in the future need to find new contract manufacturers to replace existing suppliers, increase our volumes or reduce our costs. We may not be able to find contract manufacturers that meet our needs, and even if we do, qualifying a new contract manufacturer and commencing volume production is expensive and time consuming. If we are required or elect to change contract manufacturers, we may lose revenues and our customer relationships may suffer.

### **We face intense competition from other companies and may not be able to compete successfully.**

A number of companies have developed, or are expected to develop, products that compete or will compete with our products. Some of our competitors are large companies that may enjoy significant competitive advantages over us, including:

significantly greater name recognition;

established, or larger, distribution networks;

additional product lines, and the ability to offer rebates or bundle products to offer discounts or incentives to gain a competitive advantage;

higher levels of automation and more substantial installed bases of such equipment;

more extensive research, development, sales, marketing, manufacturing and financial capabilities; and

greater financial resources allowing them to continue to improve their technology in order to compete in an evolving industry.

The markets in which we sell our products are intensely competitive, subject to rapid technological change and may be significantly affected by new product introductions and other market activities of industry participants, and these competitive pressures may reduce our gross margins. Other companies may develop products that are superior to or less expensive, or both, than our products. Improvements in existing competitive products or the introductions of new competitive products may reduce our ability to compete for sales, particularly if those competitive products demonstrate better safety or effectiveness, clinical results, ease of use or lower costs.

If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments, our business and prospects could be harmed.

**Because Gen-Probe has historically depended on a small number of customers for a significant portion of its product sales, the loss of any of these customers or any cancellation or delay of a large purchase by any of these customers could significantly reduce the revenues of the combined business.**

Historically, a limited number of customers have accounted for a significant portion of Gen-Probe's product sales, and Gen-Probe does not have any long-term commitments with these customers, other than pursuant to its collaboration agreement with Novartis. Product sales from

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Gen-Probe's blood screening collaboration with Novartis accounted for 35% of its total product sales for the first three months of 2012 and 35% of its total product sales for 2011. Gen-Probe's blood screening collaboration with Novartis is largely dependent on two significant customers in the United States, The American Red Cross and Creative Testing Solutions, although Gen-Probe does not receive any revenues directly from those entities. Novartis was Gen-Probe's only customer that accounted for greater than 10% of its total revenues during the first three months of 2012 and 2011. We anticipate that the operating results of the combined business will continue to depend, to a significant extent, upon revenues from a small number of customers. The loss of any of the combined businesses' key customers, or a significant reduction in sales volume or pricing to those customers, could significantly reduce the revenues of the combined business.

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### **Our success depends upon our ability to adapt to rapid changes in technology and customer requirements.**

The markets for our products have been characterized by rapid technological change, frequent product introductions and evolving customer requirements. These trends will likely continue into the foreseeable future. Our success depends, in part, upon our ability to enhance our existing products, successfully develop new products that meet increasing customer requirements and gain market acceptance. If we fail to do so our products may be rendered obsolete or uncompetitive by new industry standards or changing technology.

### **We will likely continue to incur significant research and development expenses, which may reduce its profitability.**

Historically, Gen-Probe and Hologic have incurred significant costs in connection with the development and improvement of their products and technologies. We expect that the R&D expense levels of the combined business will remain high as we seek to expand our product offerings and continue to develop and improve products and technologies. As a result, the combined business will need to continue to generate significant revenues to maintain current levels of profitability. We may not be able to generate sufficient revenues to maintain current levels of profitability in the future.

### **Our results of operations are subject to significant quarterly variation.**

Our results of operations have been and may continue to be subject to significant quarterly variation. Our results for a particular quarter may also vary due to a number of factors, including:

the overall state of healthcare and cost containment efforts;

the timing and level of reimbursement for our products domestically and internationally;

the development status and demand for our products;

the development status and demand for therapies to treat the health concerns addressed by our products and treatments;

economic conditions in our markets;

foreign exchange rates;

the timing of orders;

the timing of expenditures in anticipation of future sales;

the mix of products we sell and markets we serve;

regulatory approval of products;

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the introduction of new products and product enhancements by us or our competitors;

pricing and other competitive conditions;

unanticipated expenses;

complex revenue recognition rules pursuant to U.S. generally accepted accounting principles (U.S. GAAP);

asset impairments;

contingent consideration charges;

restructuring and consolidation charges; and

seasonality of sales of certain of our products.

Customers may also cancel or reschedule shipments. Production difficulties could also delay shipments. Any of these factors also could harm our business and prospects.

### **Recent changes to reclassify full-field digital mammography to permit 510(k) clearance could increase competition for our digital mammography products.**

The FDA has down-classified 2D digital mammography systems from Class III to Class II. As a result, these systems will require a 510(k) submission rather than a PMA, which will make it easier for other mammography vendors to gain approval in the United States. We anticipate that competition in the digital mammography market will intensify as more companies and products enter this market.

### **Some of our activities may subject us to risks under federal and state laws prohibiting kickbacks and false or fraudulent claims.**

We are subject to the provisions of a federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, which prohibit payments intended to induce physicians or others either to refer patients or to

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acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, laboratories and other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. Similarly, our international operations are subject to the provisions of the FCPA, which prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of influencing any act or decision of such official in his or her official capacity, inducing the official to do any act in violation of his or her lawful duty, or to secure any improper advantage in obtaining or retaining business. In many countries, the healthcare professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices is ever evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. Moreover, our failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and the imposition of civil or criminal sanctions.

**Security breaches and other disruptions could compromise our information, expose us to liability and harm our reputation and business.**

In the ordinary course of our business we collect and store sensitive data, including intellectual property, personal information, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees in our data centers and on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. We rely on commercially available systems, software, tools and monitoring to provide security for processing, transmission and storage of confidential information. Computer hackers may attempt to penetrate our computer system and, if successful, misappropriate personal or confidential business information. In addition, an associate, contractor, or other third party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. Any such compromise of our data security and access, public disclosure, or loss of personal or confidential business information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations, damage our reputation and customers' willingness to transact business with us, and subject us to additional costs and liabilities which could adversely affect our business.

**We are subject to the risk of product liability claims relating to our products.**

Our business involves the risk of product liability and other claims inherent to the medical device business. If even one of our products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. We maintain product liability insurance subject to deductibles and exclusions. There is a risk that the insurance coverage will not be sufficient to protect us from product and other liability claims, or that product liability insurance will not be available to us at a reasonable cost, if at all. An under-insured or uninsured claim could harm our business and prospects. In addition, claims could adversely affect the reputation of the related product, which could damage that product's competitive position in the market.

The sale and use of our diagnostic products could also lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect that resulted in the failure to detect a disorder for which it was being used to screen, inaccurate test results or caused injuries to a patient. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure additional coverage in the future. Also, even a meritless or unsuccessful product liability claim could be time consuming and expensive to defend, which could result in a diversion of management's attention from our business and could adversely affect the perceived safety and efficacy of our products, and could harm our business and prospects.

**We use hazardous materials and products.**

Our research and development and manufacturing processes involve the controlled use of hazardous materials, such as toxic and carcinogenic chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by federal, state and local regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of this type of accident, we could be held liable for any resulting damages, and any such liability could be extensive. We are also subject to substantial regulation relating to occupational health and safety, environmental protection, hazardous substance control, and waste management and disposal. The failure to comply with such regulations could subject us to, among other things, fines and criminal liability.





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### **We may incur losses in excess of our insurance coverage.**

Our insurance coverage includes product liability, property, fire, terrorism and business interruption policies. Our insurance coverage contains policy limits, specifications and exclusions. We believe that our insurance coverage is consistent with general practices within our industry. Nonetheless, we may incur losses of a type for which we are not covered by insurance or which exceed the limits of liability of our insurance policies. In that event, we could experience a significant loss which could have a material negative impact on our financial condition.

### **Our future success depends on the continued services of key personnel.**

The loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operational or strategic objectives. Our success also depends upon our ability to attract and retain other qualified managerial and technical personnel. Competition for such personnel, particularly software engineers and other technical personnel is intense. We may not be able to attract and retain personnel necessary for the development of our business.

### **Our failure to manage current or future alliances or joint ventures effectively may harm our business and prospects.**

We have entered into alliances, joint ventures or other business relationships. Alliances with certain partners or companies could make it more difficult for us to enter into advantageous business transactions or relationships with others. Moreover, we may not be able to:

identify appropriate candidates for alliances or joint ventures;

assure that any alliance or joint venture candidate will provide us with the support anticipated;

successfully negotiate an alliance or joint venture on terms that are advantageous to us; or

successfully manage any alliance or joint venture.

Furthermore, any alliance or joint venture may divert management time and resources. Entering into a disadvantageous alliance or joint venture, failing to manage an alliance or joint venture effectively, or failing to comply with obligations in connection therewith, could harm our business and prospects.

### **An adverse change in the projected cash flows from our business units or the business climate in which they operate, including the continuation of the current financial and economic uncertainty, could require us to record an impairment charge, which could have an adverse impact on our operating results.**

At least annually, we review the carrying value of our goodwill, and for other long-lived assets when indicators of impairment are present, to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment of the value of these assets. Conditions that could indicate impairment and necessitate an evaluation of these assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment within which we operate. In addition, the deterioration of a company's market capitalization significantly below its net book value is an indicator of impairment. We assess goodwill for impairment at the reporting unit level and in evaluating the potential impairment of goodwill, we make assumptions regarding the amount and timing of future cash flows, terminal value growth rates and appropriate discount rates. As a result of this assessment, we recorded significant impairment charges for goodwill and intangible assets in fiscal 2009 and 2010.

During the fourth quarter of fiscal 2011, we performed our annual impairment test of goodwill for our reporting units, and no additional impairment charges were required. Although we use reasonable methodologies for developing assumptions and estimates underlying the fair value calculations used in our impairment tests, these estimates are uncertain by nature and can vary from actual results. It is possible that the continuation of the current global financial and economic uncertainty could negatively affect our anticipated future cash flows, or the discount rates used to value the cash flows for each reporting unit, to such an extent that we could be required to perform an interim impairment test in fiscal 2012.

**The acquisition of Gen-Probe is expected to have a dilutive effect on our earnings per share calculated in accordance with U.S. GAAP, which may adversely affect the market price of our common stock following the acquisition.**

The acquisition of Gen-Probe is expected to have a dilutive effect on our earnings per share calculated in accordance with U.S. GAAP primarily due to the amortization of the intangible assets in connection with the acquisition. These expectations are based on preliminary estimates, which may materially change after the completion of the acquisition. We could also encounter additional transaction and integration-related costs or other factors such as the failure to realize all of the benefits anticipated in the acquisition. All of these factors could cause further dilution to our earnings per share or cause a decrease in the price of our common stock.

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### **Charges to earnings resulting from the application of the purchase method of accounting may adversely affect the market value of our common stock following the acquisition of Gen-Probe.**

In accordance with U.S. GAAP, we will account for the acquisition using the purchase method of accounting, which will result in charges to our earnings that could adversely affect the market value of our common stock following the completion of the acquisition. Under the purchase method of accounting, we will allocate the total purchase price to the assets acquired and liabilities assumed from Gen-Probe based on their estimated fair values as of the acquisition date, and record any excess of the purchase price over those fair values as goodwill. For certain tangible and intangible assets, recording their fair values as of the completion date of the acquisition will result in us incurring significant additional depreciation and/or amortization expense that exceed the combined amounts recorded by us and Gen-Probe prior to the acquisition. This increased expense will be recorded by us over the estimated useful lives of the underlying assets. In addition, to the extent the carrying value of goodwill or intangible assets post-acquisition were to become impaired, we may be required to incur charges relating to the impairment of those assets.

### **Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.**

We are subject to income taxes in both the United States and various foreign jurisdictions. We take certain income tax positions on our tax returns that we provide additional taxes if it is more likely than not they will not withstand challenge by tax authorities. We are subject to ongoing tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly evaluate the likely outcomes of these audits in order to determine the appropriateness of our tax provision and tax reserves. However, we cannot assure that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our operating results and financial condition. In addition, our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations.

Changes in tax laws or tax rulings could materially impact our effective tax rate. There are several proposals to reform U.S. tax rules being considered by U.S. law makers, including proposals that may reduce or eliminate the deferral of U.S. income tax on our unrepatriated earnings, potentially requiring those earnings to be taxed at the U.S. federal income tax rate, reduce or eliminate our ability to claim foreign tax credits, and eliminate various tax deductions until foreign earnings are repatriated to the U.S. Our future reported financial results may be adversely affected by tax rule changes which restrict or eliminate our ability to claim foreign tax credits or deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

### **Risk Relating to our Indebtedness**

#### **We are incurring significant indebtedness in order to finance the acquisition of Gen-Probe, which will limit our operating flexibility, and could adversely affect our operations and financial results and prevent us from fulfilling our obligations.**

As of August 1, 2012, following the acquisition of Gen-Probe, we have approximately \$5.0 billion of indebtedness. We also have other contractual obligations and deferred tax liabilities. This level of indebtedness and our other obligations may:

make it more difficult for us to satisfy our obligations with respect to our outstanding indebtedness;

increase our vulnerability to general adverse economic and industry conditions, including increases in interest rates;

require us to dedicate a substantial portion of our cash flow from operations to interest and principal payments on our indebtedness, which would reduce the availability of our cash flow to fund working capital, capital expenditures, expansion efforts and other general corporate purposes;

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

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place us at a competitive disadvantage compared to our competitors that have less debt; and

limit our ability to borrow additional funds for working capital, capital expenditures, general corporate purposes or acquisitions.

In addition, the terms of our financing obligations contain covenants that restrict our ability, and that of our subsidiaries, to engage in certain transactions and may impair our ability to respond to changing business and economic conditions, including, among other things, limitations on the ability to:

incur indebtedness or issue certain preferred equity;

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pay dividends, redeem stock or make other distributions or restricted payments;

make certain investments;

agree to payment restrictions affecting the restricted subsidiaries;

sell or otherwise transfer or dispose of assets, including equity interests of our subsidiaries;

enter into transactions with our affiliates;

create liens;

designate our subsidiaries as unrestricted subsidiaries;

consolidate, merge or sell substantially all of our assets; and

use the proceeds of permitted sales of our assets.

Our new senior secured credit facilities will also require us to satisfy certain financial covenants. Our ability to comply with these provisions may be affected by general economic conditions, political decisions, industry conditions and other events beyond our control. Our failure to comply with the covenants contained in the new credit facilities, including financial covenants, could result in an event of default, which could materially and adversely affect our results of operation and financial condition.

If there were an event of default under one of our debt instruments or a change of control, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately and may be cross-defaulted to other debt, including the Senior Notes. Our assets or cash flow may not be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default, and there is no guarantee that we would be able to repay, refinance or restructure the payments on those debt securities. See Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

### **We may not be able to generate sufficient cash flow to service all of our indebtedness and other obligations.**

Our ability to make payments on and to refinance our indebtedness and to fund planned capital expenditures, strategic transactions and expansion efforts will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control.

Our business may not be able to generate sufficient cash flow from operations, and we cannot assure that future borrowings will be available to us in amounts sufficient to enable us to pay our indebtedness as such indebtedness matures and to fund our other liquidity needs. If this is the case, we will need to refinance all or a portion of our indebtedness on or before maturity, and there can be no assurance that we will be able to refinance any of our indebtedness on commercially reasonable terms, or at all. We may need to adopt one or more alternatives, such as reducing or delaying planned expenses and capital expenditures, selling assets, restructuring debt, or obtaining additional equity or debt financing. These financing strategies may not be affected on satisfactory terms, if at all. Our ability to refinance our indebtedness or obtain additional financing, or to do so on commercially reasonable terms, will depend on, among other things, our financial condition at the time, restrictions in agreements governing our indebtedness, and other factors, including the condition of the financial markets and the markets in which we compete.

If we do not generate sufficient cash flow from operations, and additional borrowings, refinancings or proceeds from asset sales are not available to us, we may not have sufficient cash to enable us to meet all of our obligations.

**A significant portion of our indebtedness is subject to floating interest rates, which may expose us to higher interest payments.**

A significant portion of our indebtedness is subject to floating interest rates, which makes us more vulnerable in the event of adverse economic conditions, increases in prevailing interest rates, or a downturn in our business. As of August 1, 2012, approximately \$2.5 billion of our indebtedness, which represents the outstanding balances under our tranche A term loan facility and our tranche B term loan facility, was subject to floating interest rates. We currently have no hedging arrangements in place to mitigate the impact of higher interest rates.

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### **Risks Relating to our Common Stock and Convertible Notes**

#### **Future issuances of common stock and hedging activities may depress the trading price of our common stock and our convertible notes.**

Any future issuance of equity securities, including the issuance of shares upon conversion of our convertible notes, could dilute the interests of our existing stockholders, including holders who have received shares upon conversion of our convertible notes, and could substantially decrease the trading price of our common stock and our convertible notes. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy (including in connection with acquisitions, strategic collaborations or other transactions), to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of outstanding warrants or options or for other reasons.

In addition, the price of our common stock could also be affected by possible sales of our common stock by investors who view our convertible notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity that we expect to develop involving our common stock. The hedging or arbitrage could, in turn, affect the trading price of our convertible notes, or any common stock that note holders receive upon conversion of their notes.

#### **Future sales of our common stock in the public market or the issuance of securities senior to our common stock could adversely affect the trading price of our common stock and the value of our convertible notes and our ability to raise funds in new securities offerings.**

Future sales of our common stock, the perception that such sales could occur or the availability for future sales of shares of our common stock or securities convertible into or exercisable for our common stock could adversely affect the market prices of our common stock and the value of our convertible notes prevailing from time to time and could impair our ability to raise capital through future offerings of equity or equity-related securities. In addition, we may issue common stock or equity securities senior to our common stock in the future for a number of reasons, including to finance our operations and business strategy, to adjust our ratio of debt to equity, satisfy our obligations upon the exercise of options or for other reasons.

#### **Provisions in our charter, bylaws, indebtedness and stockholder rights plan may have the effect of discouraging advantageous offers for our business or common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.**

Our charter, bylaws, and the provisions of the Delaware General Corporation Law include provisions that may have the effect of discouraging or preventing a change of control. Our indebtedness also contains provisions which either accelerate or require us to offer to repurchase the indebtedness at a premium upon a change of control. In addition, we have a stockholder rights plan that may have the effect of discouraging or preventing a change of control. These provisions could limit the price that our stockholders might receive in the future for shares of our common stock.

#### **Our stock price is volatile.**

The market price of our common stock has been, and may continue to be, highly volatile. We believe that a variety of factors could cause the price of our common stock to fluctuate, perhaps substantially, including:

new, or changes in, recommendations, guidelines or studies that could affect the use of our products;

announcements and rumors of developments related to our business, including changes in reimbursement rates or regulatory requirements, proposed and completed acquisitions, or the industry in which we compete;

published studies and reports relating to the comparative efficacy of products and markets in which we participate;

quarterly fluctuations in our actual or anticipated operating results and order levels;

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general conditions in the worldwide economy;

announcements of technological innovations;

new products or product enhancements by us or our competitors;

developments in patents or other intellectual property rights and litigation;

developments in relationships with our customers and suppliers;

the implementation of healthcare reform legislation and the adoption of additional reform legislation in the future, and;

the success or lack of success of integrating our acquisitions.

The price of our common stock also may be adversely affected by the amount of common stock issuable upon conversion of our convertible notes. In addition, in recent years the stock market in general and the markets for shares of



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high-tech companies, have experienced extreme price fluctuations which have often been unrelated to the operating performance of affected companies. Any such fluctuations in the future could adversely affect the market price of our common stock, and the market price of our common stock may decline.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.*****Issuer's Purchases of Equity Securities***

For the majority of restricted stock units granted, the number of shares issued on the date that the restricted stock units vest is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate taxing authorities on behalf of our employees. The following table sets forth information about deemed repurchases of our common stock to cover employee income tax withholding obligations in connection with the vesting of restricted stock units under our equity incentive plans for the three months ended June 23, 2012:

Period of Repurchase		Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased As Part of Publicly Announced Program
March 25, 2012	April 21, 2012		\$	
April 22, 2012	May 19, 2012	539	17.10	
May 20, 2012	June 23, 2012	97	16.92	
Total		636	\$ 17.07	

**Table of Contents****Item 6. Exhibits****(a) Exhibits**

Exhibit Number	Exhibit Description	Incorporated by Reference	
		Filing Date/	Period End Date
4.1	Indenture dated August 1, 2012 by and among Hologic, Inc., the guarantors party thereto and Wells Fargo Bank, National Association, as Trustee.	8-K	08/01/2012
4.2	Forms of 6.25% Senior Note due 2020 (included in Exhibit 4.1).	8-K	08/01/2012
4.3	Exchange and Registration Rights Agreement dated August 1, 2012 by and among Hologic, Inc., certain of its subsidiaries and Goldman, Sachs & Co.	8-K	08/01/2012
10.1	Amended and Restated Commitment Letter dated May 11, 2012, by and among Hologic, Inc., Goldman Sachs Bank USA, Goldman Sachs Lending Partners LLC, JPMorgan Chase Bank, N.A., J.P. Morgan Securities LLC, and Citigroup Global Markets Inc.	8-K	05/17/2012
10.2	Retention and Severance Agreement dated July 10, 2012, by and between Hologic, Inc. and Carl W. Hull.	8-K	07/12/2012
10.3	Change of Control Agreement dated July 10, 2012, by and between Hologic, Inc. and Carl W. Hull.	8-K	07/12/2012
10.4	Purchase Agreement dated July 19, 2012, by and among Hologic, Inc., certain guarantors, and Goldman, Sachs & Co.	8-K	07/19/2012
10.5	Credit and Guaranty Agreement dated August 1, 2012 by and among Hologic, Inc., the guarantors party thereto and Goldman Sachs Bank USA.	8-K	08/01/2012
10.6	Pledge and Security Agreement dated August 1, 2012 by and among Hologic, Inc., the guarantors party thereto and Goldman Sachs Bank USA.	8-K	08/01/2012
10.7	Restricted Stock Unit Grant.	8-K	08/01/2012
31.1*	Certification of Hologic's CEO pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
31.2*	Certification of Hologic's CFO pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
32.1**	Certification of Hologic's CEO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
32.2**	Certification of Hologic's CFO pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
101.INS	XBRL Instance Document		
101.SCH	XBRL Taxonomy Extension Schema Document		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document		
101.LAB	XBRL Taxonomy Extension Label Linkbase Document		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document		
101.DEF	XBRL Taxonomy Extension Definition		

\* Filed herewith.

\*\* Furnished herewith.



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**HOLOGIC, INC.**

**SIGNATURES**

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

Hologic, Inc.  
(Registrant)

August 2, 2012  
Date

/s/ ROBERT A. CASCELLA  
**Robert A. Cascella**  
**Chief Executive Officer**

August 2, 2012  
Date

/s/ GLENN P. MUIR  
**Glenn P. Muir**  
**Executive Vice President, Finance and Administration,**  
**and Chief Financial Officer**  
**(Principal Financial Officer)**