INTEGRA LIFESCIENCES HOLDINGS CORP

Form 10-Q October 24, 2012 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 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 September 30, 2012

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

For the transition period from to COMMISSION FILE NO. 0-26224

INTEGRA LIFESCIENCES HOLDINGS CORPORATION (EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE 51-0317849

(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) (I.R.S. EMPLOYER IDENTIFICATION NO.)

311 ENTERPRISE DRIVE

PLAINSBORO, NEW JERSEY

08536

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (609) 275-0500

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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 x No o

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

Large accelerated filer x Accelerated filer o

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

Smaller reporting company o

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

The number of shares of the registrant's Common Stock, \$0.01 par value, outstanding as of October 22, 2012 was 27,045,530.

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#### PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (UNAUDITED)

(In thousands, except per share amounts)

	Three Months Ended September		Nine Months Ended September		
	30,		30,		
	2012	2011	2012	2011	
Total Revenue	\$210,084	\$202,185	\$616,439	\$576,555	
Costs and Expenses:					
Cost of goods sold	79,548	78,651	232,497	216,410	
Research and development	13,105	13,187	38,148	38,049	
Selling, general and administrative	93,077	87,508	276,585	263,324	
Intangible asset amortization	4,618	4,548	13,985	11,609	
Total costs and expenses	190,348	183,894	561,215	529,392	
Operating income	19,736	18,291	55,224	47,163	
Interest income	100	154	893	354	
Interest expense	(5,549)	(7,587)	(20,581)	(19,778)	
Other income (expense), net	(31)	429	(118)	379	
Income before income taxes	14,256	11,287	35,418	28,118	
Income tax (benefit) expense	1,045	44	7,000	4,689	
Net income	\$13,211	\$11,243	\$28,418	\$23,429	
Basic net income per common share	\$0.46	\$0.39	\$1.00	\$0.80	
Diluted net income per common share	\$0.46	\$0.39	\$0.99	\$0.79	
Weighted average common shares outstanding	!				
(See Note 12):					
Basic	28,446	28,583	28,403	29,234	
Diluted	28,777	29,029	28,629	29,820	
Comprehensive income (loss) (See Note 13)	\$17,106	\$(7,894)	\$28,016	\$21,945	

The accompanying notes are an integral part of these condensed consolidated financial statements.

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# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands)

	September 30, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	\$125,718	\$100,808
Trade accounts receivable, net of allowances of \$6,695 and \$6,978	119,527	118,129
Inventories, net	169,376	171,261
Deferred tax assets	64,575	36,155
Prepaid expenses and other current assets	14,366	25,904
Total current assets	493,562	452,257
Property, plant and equipment, net	161,189	131,383
Intangible assets, net	218,345	237,122
Goodwill	292,426	292,980
Deferred tax assets	8,028	21,477
Other assets	11,956	13,128
Total assets	\$1,185,506	\$1,148,347
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable, trade	\$43,239	\$27,656
Deferred revenue	3,645	4,543
Accrued compensation	28,099	28,010
Accrued expenses and other current liabilities	37,591	41,659
Total current liabilities	112,574	101,868
Long-term borrowings under senior credit facility	321,875	179,688
Long-term convertible securities	195,860	352,576
Deferred tax liabilities	14,893	5,726
Other liabilities	13,603	15,851
Total liabilities	\$658,805	\$655,709
Commitments and contingencies		
Stockholders' Equity:		
Preferred Stock; no par value; 15,000 authorized shares; none outstanding		
Common stock; \$0.01 par value; 60,000 authorized shares; 35,905 and 35,734	359	357
issued at September 30, 2012 and December 31, 2011, respectively	339	331
Additional paid-in capital	613,721	607,676
Treasury stock, at cost; 8,903 shares at September 30, 2012 and December 31,	(367,121	(367,121)
2011		
Accumulated other comprehensive (loss):	(9,495	) (9,093
Retained earnings	289,237	260,819
Total stockholders' equity	526,701	492,638
Total liabilities and stockholders' equity	\$1,185,506	\$1,148,347

The accompanying notes are an integral part of these condensed consolidated financial statements.

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### INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED) (In thousands)

	Nine Months Ended September 30		
ODED A TIME A CTIVITIES.	2012	2011	
OPERATING ACTIVITIES:	¢20 410	¢22.420	
Net income	\$28,418	\$23,429	
Adjustments to reconcile net income to net cash provided by operating activities		27 202	
Depreciation and amortization	39,122	37,303	
Deferred income tax provision (benefit)	,	(4,450 )	
Amortization of debt issuance costs	2,103	2,630	
Non-cash interest expense	8,284	7,119	
Payment of accreted interest	(30,617 )	_	
Loss on disposal of property and equipment	807		
Share-based compensation	6,632	18,897	
Excess tax benefits from stock-based compensation arrangements	(432)	(844)	
Changes in assets and liabilities, net of business acquisitions:			
Accounts receivable	,	(777)	
Inventories	1,080	(6,788)	
Prepaid expenses and other current assets	8,148	(546)	
Other non-current assets	,	(61)	
Accounts payable, accrued expenses and other current liabilities	6,528	(4,185)	
Deferred revenue	(913	(816)	
Other non-current liabilities	(1,263)	(1,278)	
Net cash provided by operating activities	\$62,503	\$69,633	
INVESTING ACTIVITIES:			
Purchases of property and equipment	(44,359)	(25,381)	
Cash used in business acquisition	(2,177)	(149,420 )	
Purchases of short-term investments	(67,907)		
Maturities of short-term investments	64,940	_	
Net cash used in investing activities	\$(49,503)	\$(174,801)	
FINANCING ACTIVITIES:			
Borrowings under senior credit facility	155,000	135,000	
Repayments under senior credit facility	(12,812	(190,625)	
Proceeds from liability component of convertible notes	<del></del>	186,830	
Proceeds from equity component of convertible notes		43,170	
Proceeds from sale of stock purchase warrants		28,451	
Payment of liability component of convertible notes	(134,383		
Purchase of option hedge on convertible notes		(42,895)	
Debt issuance costs		(8,064)	,
Purchases of treasury stock	_	(69,011)	,
Proceeds from exercised stock options	696	3,544	
Excess tax benefits from stock-based compensation arrangements	432	844	
Net cash provided by (used in) financing activities	8,933	87,244	
Effect of exchange rate changes on cash and cash equivalents	2,977	152	
Net change in cash and cash equivalents	24,910	(17,772)	
Cash and cash equivalents at beginning of period	100,808	128,763	
cush and cush equivalents at organism of period	100,000	120,703	

Cash and cash equivalents at end of period

\$125,718

\$110,991

The accompanying notes are an integral part of these condensed consolidated financial statements.

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# INTEGRA LIFESCIENCES HOLDINGS CORPORATION NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. BASIS OF PRESENTATION

General

The terms "we," "our," "us," "Company" and "Integra" refer to Integra LifeSciences Holdings Corporation, a Delaware corporation, and its subsidiaries unless the context suggests otherwise.

In the opinion of management, the September 30, 2012 unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows of the Company. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K. The December 31, 2011 condensed consolidated balance sheet was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States. Operating results for the three- and nine-month periods ended September 30, 2012 are not necessarily indicative of the results to be expected for the entire year.

The preparation of consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, the disclosure of contingent liabilities, and the reported amounts of revenues and expenses. Significant estimates affecting amounts reported or disclosed in the consolidated financial statements include allowances for doubtful accounts receivable and sales returns and allowances, net realizable value of inventories, valuation of intangible assets including in-process research and development, amortization periods for acquired intangible assets, discount rates and estimated projected cash flows used to value and test impairments of long-lived assets and goodwill, estimates of projected cash flows and depreciation and amortization periods for long-lived assets, computation of taxes, valuation allowances recorded against deferred tax assets, the valuation of stock-based compensation, valuation of pension assets and liabilities, valuation of derivative instruments, valuation of the equity component of convertible debt instruments, and loss contingencies. These estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the current circumstances. Actual results could differ from these estimates.

Certain amounts from the prior year's financial statements have been reclassified in order to conform to the current year's presentation.

Recently Issued and Adopted Accounting Standards

On July 27, 2012, the Financial Accounting Standard Board issued Accounting Standards Update No. 2012-02, Testing Indefinite-Lived Intangible Assets for Impairment. The revised standard is intended to reduce the cost and complexity of testing indefinite-lived intangible assets other than goodwill for impairment by providing entities with an option to perform a "qualitative" assessment to determine whether further impairment testing is necessary. The revised standard allows an entity first to assess qualitative factors to determine whether events and circumstances indicate that it is more likely than not (that is, a likelihood of more than 50 percent) that an indefinite-lived intangible asset is impaired. If it is more likely than not that the asset is impaired, the entity must calculate the fair value of the asset, compare the fair value to its carrying amount, and record an impairment charge, if the carrying amount exceeds fair value. However, if an entity concludes that it is not more likely than not that the asset is impaired, no further action is required. The qualitative assessment is not an accounting policy election. An entity can choose to perform the qualitative assessment for any indefinite-lived intangible assets. Moreover, an entity can bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to the quantitative impairment test, and then choose to perform the qualitative assessment in any subsequent period. The revised standard is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. However, an entity can choose to early adopt the revised standard even if its annual or interim

impairment test date is before July 27, 2012 (the date on which the revised standard was issued), provided that its financial statements for the most recent annual or interim period have not yet been issued. The Company elected to adopt this standard early and such adoption did not have a material impact on the Company's financial statements.

#### 2. BUSINESS ACQUISITIONS

Ascension Orthopedics, Inc.

On September 23, 2011, the Company acquired Ascension Orthopedics, Inc. ("Ascension") for \$66.0 million, which includes amounts paid for working capital adjustments of \$0.2 million less amounts received from escrow of \$0.7 million. Ascension,

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based in Austin, Texas, develops and distributes a range of implants for the shoulder, elbow, wrist, hand, foot and ankle.

The following summarizes the final allocation of the purchase price based on fair value of the assets acquired and liabilities assumed:

	Final	
	Purchase Price	
	Allocation	
	(Dollars in thousands)	
Cash	\$627	
Inventory	12,760	
Accounts receivable	2,917	
Other current assets	2,398	
Property, plant and equipment	4,649	
Other long-term assets	70	
Deferred tax asset — long term	12,543	
Intangible assets		Wtd. Avg. Life:
Technology	7,885	10 years
Customer relationships	5,750	12 years
In-process research and development	1,739	Indefinite
Supplier relationship	4,510	10 years
Trade name	560	1 year
Goodwill	15,460	
Total assets acquired	71,868	
Accounts payable and other liabilities	5,827	
Net assets acquired	\$66,041	

Management determined the preliminary fair value of net assets acquired during the third quarter of 2011 and finalized the working capital adjustment in the second quarter of 2012. Measurement period adjustments included above reflected a decrease in the total fair value of inventory acquired and a decrease in the value of long-term deferred tax assets acquired which was recorded in the fourth quarter of 2011. The measurement period adjustments were made to reflect facts and circumstances existing as of the acquisition date, and did not result from intervening events subsequent to the acquisition date. These adjustments did not have a significant impact on the Company's previously reported consolidated financial statements and, therefore, the Company has not retrospectively adjusted those financial statements.

The goodwill recorded in connection with this acquisition is based on (i) expected cost savings, operating synergies and other benefits expected to result from the combined operations, (ii) the value of the going-concern element of Ascension's existing business (that is, the higher rate of return on the assembled net assets versus if the Company had acquired all of the net assets separately), and (iii) intangible assets that do not qualify for separate recognition such as Ascension's assembled workforce. The goodwill acquired will not be deductible for tax purposes. SeaSpine, Inc.

On May 23, 2011, the Company acquired all of the outstanding common stock of SeaSpine, Inc. ("SeaSpine") for \$89.0 million, less working capital adjustments of \$0.3 million and indemnification holdbacks totaling \$7.4 million of which \$4.9 million remains accrued at September 30, 2012. SeaSpine is based in Vista, California and designs, develops and manufactures spinal fixation products and synthetic bone substitute products.

The following summarizes the final allocation of the purchase price based on fair value of the assets acquired and liabilities assumed:

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	Final	
	Purchase Price	
	Allocation	
	(Dollars in thousands)	
Cash	\$201	
Inventory	14,900	
Accounts receivable	7,608	
Other current assets	623	
Property, plant and equipment	9,177	
Deferred tax asset—long term	302	
Intangible assets:		Wtd. Avg. Life:
Technology	3,000	8 years
Customer relationships	41,200	13 years
Non-compete agreements	1,900	4 years
Trade name	300	1 year
Goodwill	14,572	
Total assets acquired	93,783	
Accounts payable and other liabilities	5,108	
Net assets acquired	\$88,675	

Management determined the preliminary fair value of net assets acquired during the second quarter of 2011 and finalized the working capital adjustment in the first quarter of 2012. Measurement period adjustments included above reflect a decrease in the total fair value of consideration to be transferred pursuant to the final working capital adjustment. These measurement period adjustments were made to reflect facts and circumstances existing as of the acquisition date, and did not result from intervening events subsequent to the acquisition date. This adjustment did not have a significant impact on the Company's previously reported consolidated financial statements and, therefore, the Company has not retrospectively adjusted those financial statements.

The goodwill recorded in connection with this acquisition is based on the benefits the Company expects to generate from SeaSpine's future cash flows. For tax purposes, the Company is treating the acquisition as an asset acquisition; therefore, the goodwill will be deductible for tax purposes.

#### Pro Forma Results

The following unaudited pro forma financial information summarizes the results of operations for the three and nine months ended September 30, 2011 as if the acquisitions completed by the Company during 2011 had been completed as of January 1, 2010. The pro forma results are based upon certain assumptions and estimates, and they give effect to actual operating results prior to the acquisitions and adjustments to reflect (i) increased interest expense, depreciation expense, intangible asset amortization and fair value inventory step-up, (ii) decreases in certain expenses that will not be recurring in the post-acquisition entity, and (iii) income taxes at a rate consistent with the Company's statutory rate. No effect has been given to other cost reductions or operating synergies. As a result, these pro forma results do not necessarily represent results that would have occurred if the acquisitions had taken place on the basis assumed above, nor are they indicative of the results of future combined operations.

111100 1:10111111	1 11110 1110111111111111111111111111111
Ended	Ended
September 30,	September 30,
2011	2011
(in thousands excep	t per share amounts)

Nine Months

Three Months

Total Revenue \$608,375 \$206,048

Net income \$9,416 \$17,690

Net income per share

Basic	\$0.33	\$0.61
Diluted	\$0.32	\$0.59

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#### 3. INVENTORIES

Inventories, net consisted of the following:

	September 30,	December 31,
	2012	2011
	(In thousands)	
Finished goods	\$103,870	\$106,972
Work-in process	37,515	36,070
Raw materials	27,991	28,219
	\$169,376	\$171.261

#### 4. SHORT-TERM INVESTMENTS

The Company's short-term investments consist entirely of time deposits held by investment grade banks. These investments have maturity dates ranging from approximately three months to six months from the original date of purchase. The carrying value of these short-term investments is a reasonable estimate of their fair value. All such investments matured during the third quarter of 2012.

#### 5. GOODWILL AND OTHER INTANGIBLE ASSETS

The Company revised its operating segments and reporting segments in connection with the change in the Company's Chief Executive Officer (who serves as the Company's chief operating decision maker) effective January 3, 2012. As a result, the Company reassigned the goodwill to these new reportable segments based on the relative fair value of the Company's eight underlying reporting units as of January 1, 2012. On July 31, 2012, the Company performed the annual goodwill impairment test. The Company first assessed the qualitative factors to determine whether it is more likely than not that the fair value of the reporting units is less than their carrying amounts. The Company performed this qualitative assessment for seven reporting units that each had an estimated fair value that was in excess of its carrying value by a significant amount. For each reporting unit, the Company weighed the relative impact of factors that are specific to the reporting unit as well as industry and macroeconomic factors. The reporting unit specific factors that were considered included the results of the most recent impairment tests, as well as financial performance and changes to the reporting units' carrying amounts since the most recent impairment tests. The Company concluded that each of the reporting unit specific and industry factors had either a positive or neutral impact on their fair values. The Company also determined that macroeconomic factors during 2012 did not have a significant impact on the discount rates and growth rates used for the January 1 tests. Based on the qualitative assessment, the Company concluded that for these seven reporting units, it is more likely than not that their carrying values are less than their fair values at July 31, 2012.

The Company performed the first step of the goodwill impairment test for its U.S. Spine business. This component has \$31.7 million of allocated goodwill. As a result of the annual impairment assessment, the Company determined that the fair value exceeded its carrying value by approximately 13% at July 31, 2012. However, if future results do not meet or exceed the Company's forecasts, or if unfavorable changes occur in the weighted-average cost of capital, growth assumptions for future revenue, terminal value growth rate and/or forecasted cash flows utilized in the discounted cash flow analysis, the Company may record an impairment of this goodwill at a future date. Changes in the carrying amount of goodwill for the nine months ended September 30, 2012 were as follows:

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	U.S. Neurosurgery	U.S. / Instruments	U.S. Extremities	U.S. Spine and Other	International	Total	
	(In thousands	s)					
Goodwill, gross	\$93,913	\$57,270	\$60,544	\$55,693	\$25,560	\$292,980	
Accumulated impairment losses							
Goodwill at December 31, 2011	93,913	57,270	60,544	55,693	25,560	292,980	
SeaSpine, Inc. working capital adjustment				289		289	
Ascension Orthopedics, Inc.							
working capital adjustment and			(448)			(448	)
other							
Foreign currency translation					(395)	(395	)
Balance, September 30, 2012	\$93,913	\$57,270	\$60,096	\$55,982	\$25,165	\$292,426	

The components of the Company's identifiable intangible assets were as follows:

	Weighted	September 30	0, 2012			December 31	, 2011		
	Average Life	Cost	Accumulat Amortizati		NAT	Cost	Accumulate Amortization		Net
	(Dollars in	Thousands)							
Completed technology	11 years	\$75,553	\$(36,707	)	\$38,846	\$75,990	\$(32,157	)	\$43,833
Customer relationships	11 years	147,550	(66,783	)	80,767	147,230	(57,348	)	89,882
Trademarks/brand names	32 years	33,764	(14,116	)	19,648	33,669	(10,897	)	22,772
Trademarks/brand names	Indefinite	48,484	_		48,484	48,484	_		48,484
Supplier relationships	26 years	33,810	(5,783	)	28,027	33,810	(5,389	)	28,421
All other (1)	6 years	5,582 \$344,743	(3,009 \$(126,398	)	2,573 \$218,345	11,434 \$350,617	(7,704 \$(113,495	)	3,730 \$237,122

<sup>(1)</sup> At September 30, 2012 and December 31, 2011, all other included in-process research and development of \$1.7 million, which was indefinite lived.

During the nine months ended September 30, 2012, the Company recorded impairment charges of \$0.1 million in cost of goods sold related to technology assets whose related products are being discontinued.

Based on quarter-end exchange rates, annual amortization expense is expected to approximate \$25.1 million in 2012, \$19.0 million in 2013, \$18.1 million in 2014, \$16.3 million in 2015 and \$14.0 million in 2016. Identifiable intangible assets are initially recorded at fair market value at the time of acquisition using an income or cost approach.

#### 6. DEBT

Amended and Restated Senior Credit Agreement

On August 10, 2010, the Company entered into an amended and restated credit agreement with a syndicate of lending banks (the "Senior Credit Facility"), it amended the Senior Credit Facility on June 8, 2011, and further amended it on May 11, 2012.

The June 8, 2011 amendment:

- increased the revolving credit component from \$450 million to \$600 million and eliminated the \$150 million term loan component that existed under the original amended and restated credit agreement;
- ii. allows the Company to further increase the size of the revolving credit component by an aggregate of \$200 million with additional commitments;
- iii. provides the Company with decreased borrowing rates and annual commitment fees, and provides more favorable financial covenants; and
- iv. extended the maturity date from August 10, 2015 to June 8, 2016.

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On May 11, 2012, the Company entered into another amendment to the Senior Credit Facility (the "2012 Amendment"). The 2012 Amendment modified certain financial and negative covenants. The 2012 Amendment provides that the Company's Maximum Consolidated Total Leverage Ratio (a measure of net debt to consolidated EBITDA, in each case as defined in the Senior Credit Facility, as amended) during any consecutive four quarter period should not be greater than 3.75 to 1.00 during any such period ending on December 31, 2013 (instead of March 31, 2012). In addition, when calculating consolidated EBITDA for any period, the 2012 Amendment permits the addition of certain costs and expenses in the calculation of consolidated net income for such period, to the extent deducted in the calculation of consolidated net income. The Senior Credit Facility is collateralized by substantially all of the assets of the Company's U.S. subsidiaries, excluding intangible assets. The Senior Credit Facility is subject to various financial and negative covenants and at September 30, 2012, the Company was in compliance with all such covenants. Borrowings under the Senior Credit Facility currently bear interest, at the Company's option, at a rate equal to (i) the Eurodollar Rate (as defined in the Senior Credit Facility, which definition has not changed) in effect from time to time plus the applicable rate (ranging from 1.00% to 1.75%) or (ii) the highest of (x) the weighted average overnight Federal funds rate, as published by the Federal Reserve Bank of New York, plus 0.5%, (y) the prime lending rate of Bank of America, N.A. or (z) the one-month Eurodollar Rate plus 1.0%. The applicable rates are based on the Company's consolidated total leverage ratio (defined as the ratio of (a) consolidated funded indebtedness less cash in excess of \$40 million that is not subject to any restriction of the use or investment thereof to (b) consolidated EBITDA) at the time of the applicable borrowing.

The Company will also pay an annual commitment fee (ranging from 0.15% to 0.30%, based on the Company's consolidated total leverage ratio) on the daily amount by which the revolving credit facility exceeds the outstanding loans and letters of credit under the credit facility.

At September 30, 2012 and December 31, 2011, there was \$321.9 million and \$179.7 million outstanding, respectively, under the Senior Credit Facility at a weighted average interest rate of 1.8% and 2.0%, respectively. At September 30, 2012, there was approximately \$278.1 million available for borrowing under the Senior Credit Facility. The fair value of outstanding borrowings under the Senior Credit Facility at September 30, 2012 was approximately \$299.1 million. The fair value of the Senior Credit Facility was determined by using a discounted cash flow model based on current market interest rates available to the Company. These inputs are corroborated by observable market data for similar liabilities and therefore classified within Level 2 of the fair value hierarchy. Level 2 inputs represent inputs that are observable for the asset or liability, either directly or indirectly and are other than active market observable inputs that reflect unadjusted quoted prices for identical assets or liabilities. The Company considers the balance to be long term in nature based on its current intent and ability to repay the borrowing outside of the next twelve-month period.

#### 2016 Convertible Senior Notes

On June 15, 2011, the Company issued \$230.0 million aggregate principal amount of its 1.625% Convertible Senior Notes due 2016 (the "2016 Notes"). The 2016 Notes mature on December 15, 2016, and bear interest at a rate of 1.625% per annum payable semi-annually in arrears on December 15 and June 15 of each year. The portion of the debt proceeds that was classified as equity at the time of the offering was \$43.2 million, an equivalent of that amount is being amortized to interest expense using the effective interest method through December 2016. The effective interest rate implicit in the liability component is 5.6%. The fair value of the liability of the 2016 Notes was determined using a discounted cash flow model based on current market interest rates available to the Company. These inputs are corroborated by observable market data for similar liabilities and therefore classified within Level 2. At September 30, 2012, the carrying amount of the liability component was \$195.9 million, the remaining unamortized discount was \$34.1 million, and the principal amount outstanding was \$230.0 million. The fair value of the liability component was \$190.6 million, the remaining unamortized discount was \$39.4 million and the principal amount outstanding was \$230.0 million and the principal amount outstanding was \$230.0 million.

The 2016 Notes are senior, unsecured obligations of the Company, and are convertible into cash and, if applicable, shares of its common stock based on an initial conversion rate, subject to adjustment of 17.4092 shares per \$1,000 principal amount of 2016 Notes (which represents an initial conversion price of approximately \$57.44 per share). The

Company will satisfy any conversion of the 2016 Notes with cash up to the principal amount of the 2016 Notes pursuant to the net share settlement mechanism set forth in the indenture and, with respect to any excess conversion value, with shares of the Company's common stock. The 2016 Notes are convertible only in the following circumstances: (1) if the closing sale price of the Company's common stock exceeds 150% of the conversion price during a period as defined in the indenture; (2) if the average trading price per \$1,000 principal amount of the 2016 Notes is less than or equal to 98% of the average conversion value of the 2016 Notes during a period as defined in the indenture; (3) at any time on or after June 15, 2016; or (4) if specified corporate

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transactions occur. The issue price of the 2016 Notes was equal to their face amount, which is also the amount holders are entitled to receive at maturity if the 2016 Notes are not converted. As of September 30, 2012, none of these conditions existed with respect to the 2016 Notes and as a result, the 2016 Notes are classified as long term. In connection with the issuance of the 2016 Notes, the Company entered into call transactions and warrant transactions, primarily with affiliates of the initial purchasers of such notes (the "hedge participants"). The initial strike price of the call transaction is approximately \$57.44 per share, subject to customary anti-dilution adjustments. The initial strike price of the warrant transaction is approximately \$70.05 per share, subject to customary anti-dilution adjustments.

#### 2012 Senior Convertible Notes

On June 11, 2007, the Company issued \$165.0 million aggregate principal amount of its 2012 Notes (the "2012 Notes"). In June 2012, the Company repaid the 2012 Notes at maturity with long-term borrowings from its Senior Credit Facility and cash on hand. The related bond hedge contracts will terminate in components over the 100 trading day period commencing 90 days after the maturity of the 2012 Note.

#### Convertible Note Interest

The interest expense components of the Company's convertible notes are as follows:

	Three Months Ended September 30,		Nine Months E	nded September
	2012 2011		2012	2011
2016 Notes:	(amounts in the	ousands)		
Amortization of the discount on the liability component	\$1,788	\$1,691	\$5,289	\$2,026
Cash interest related to the contractual interest coupon	934	934	2,803	1,090
Total	\$2,722	\$2,625	\$8,092	\$3,116
2012 Notes: Amortization of the discount on the liability				
component	<b>\$</b> —	\$1,726	\$2,995	\$5,093
Cash interest related to the contractual interest	_	980	1,633	2,940
Total Total	<b>\$</b> —	\$2,706	\$4,628	\$8,033

#### 7. DERIVATIVE INSTRUMENTS

**Interest Rate Hedging** 

The Company's interest rate risk relates to U.S. dollar denominated variable LIBOR interest rate borrowings. The Company uses an interest rate swap derivative instrument entered into on August 10, 2010 with an effective date of December 31, 2010 to manage its earnings and cash flow exposure to changes in interest rates by converting a portion of its floating-rate debt into fixed-rate debt beginning on December 31, 2010. This interest rate swap expires on August 10, 2015.

The Company designates this derivative instrument as a cash flow hedge. The Company records the effective portion of any change in the fair value of a derivative instrument designated as a cash flow hedge as unrealized gains or losses in accumulated other comprehensive income ("AOCI"), net of tax, until the hedged item affects earnings, at which point the effective portion of any gain or loss will be reclassified to earnings. If the hedged cash flow does not occur, or if it becomes probable that it will not occur, the Company will reclassify the amount of any gain or loss on the related cash flow hedge to interest expense at that time.

The Company expects that approximately \$2.0 million of pre-tax losses recorded as net in AOCI related to the interest rate hedge could be reclassified to earnings within the next twelve months.

Foreign Currency Hedging

From time to time the Company enters into foreign currency hedge contracts intended to protect the U.S. dollar value of certain forecasted foreign currency denominated transactions. The Company records the effective portion of any change in the fair value of foreign currency cash flow hedges in AOCI, net of tax, until the hedged item affects earnings. Once the related hedged item affects earnings, the Company reclassifies the effective portion of any related unrealized gain or loss on the foreign currency cash flow hedge to earnings. If the hedged forecasted transaction does not occur, or if it becomes probable that it will not occur, the Company will reclassify the amount of any gain or loss on the related cash flow hedge to earnings at that time.

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The success of the Company's hedging program depends, in part, on forecasts of certain activity denominated in euros. The Company may experience unanticipated currency exchange gains or losses to the extent that there are differences between forecasted and actual activity during periods of currency volatility. In addition, changes in currency exchange rates related to any unhedged transactions may affect its earnings and cash flows.

#### Counterparty Credit Risk

The Company manages its concentration of counterparty credit risk on its derivative instruments by limiting acceptable counterparties to a group of major financial institutions with investment grade credit ratings, and by actively monitoring their credit ratings and outstanding positions on an ongoing basis. Therefore, the Company considers the credit risk of the counterparties to be low. Furthermore, none of the Company's derivative transactions are subject to collateral or other security arrangements, and none contain provisions that depend upon the Company's credit ratings from any credit rating agency.

#### Fair Value of Derivative Instruments

The Company has classified all of its derivative instruments within Level 2 of the fair value hierarchy because observable inputs are available for substantially the full term of the derivative instruments. The fair value of the foreign currency forward exchange contracts related to inventory purchases is determined by comparing the forward rate as of the period end and the settlement rate specified in each contract. The fair value of the interest rate swaps was developed using a market approach based on publicly available market yield curves and the terms of the related swap. The Company performs ongoing assessments of counterparty credit risk.

The following table summarizes the fair value, notional amounts presented in U.S. dollars, and presentation in the consolidated balance sheet for derivatives designated as hedging instruments as of September 30, 2012 and December 31, 2011:

	Fair Value as or	f	Notional Amount as of				
Location on Balance Sheet (1):	September 30,	December 31,	September 30,	December 31,			
Location on Barance Sheet V.	2012	2011	2012	2011			
	(In thousands)						
Derivatives designated as hedges — Liabilities:							
Interest rate swap — Accrued expenses and other	\$1,954	\$1,634					
current liabilities <sup>(2)</sup>	Ψ1,551	Ψ1,05					
Foreign currency forward contracts — Accrued		108	\$	\$1,597			
expenses and other current liabilities		100	ψ—	Ψ1,377			
Interest rate swap — Other liabilities	2,688	2,458					
Total Derivatives designated as hedges — Liabilities	es\$4,642	\$4,200					

<sup>(1)</sup> The Company classifies derivative assets and liabilities as current based on the cash flows expected to be incurred within the following 12 months.

The following presents the effect of derivative instruments designated as cash flow hedges on the accompanying consolidated statements of operations during the three and nine months ended September 30, 2012 and 2011:

At September 30, 2012 and December 31, 2011, the notional amount related to the Company's sole interest rate (2) swap was \$131.3 million and \$139.7 million, respectively. In the next twelve months, the Company expects to reduce the notional amount by \$14.1 million.

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	D-1 ! A	~	Amount of	,		•			
	Balance in A Beginning of		Recognized in	•	Reclassified from AOCI into	m	Balance in A	OC	Location in Statements of
	Quarter		AOCI-	1	Earnings-Effecti	ive	End of Quarte	er	Operations
	Quarter		Effective Por	tio	_				Operations
	(In thousands	3)							
Three Months Ended September 30, 2012	•								
Forward currency forward contracts	(176	)	(9	)	(6	)	(179	)	Costs of goods sold
Interest rate swap	(4,374	)	(744	)	(476	)	(4,642	)	Interest (expense)
	(4,550	)	(753	)	(482	)	(4,821	)	
Three Months Ended September 30, 2011									
Interest rate swap	(1,908	)	(3,116	)	(592	)	(4,432	)	Interest (expense)
	Balance in A Beginning of Year	O(	Amount of		Amount of Gain (Loss) Reclassified from AOCI into	m	Balance in AOCI End of Quarte	er	Location in Statements of Operations
	(In thousands	(3)							
Nine Months Ended September 30, 2012									
Forward currency forward contracts	(216	)	(140	)	(177	)	(179	)	Cost of goods sold
Interest rate swap	(4,092	)	(1,952	)	(1,402	)	(4,642	)	Interest (expense)
	(4,308	)	(2,092	)	(1,579	)	(4,821	)	
Nine Months Ended September 30, 2011									
Interest rate swap	(270	)	(5,897	)	(1,735	)	(4,432	)	Interest (expense)

The Company recognized no gains or losses resulting from ineffectiveness of cash flow hedges during the three and nine months ended September 30, 2012 and 2011.

#### 8. STOCK-BASED COMPENSATION

As of September 30, 2012, the Company had stock options, restricted stock awards, performance stock awards, contract stock awards and restricted stock unit awards outstanding under five plans, the 1998 Stock Option Plan (the "1998 Plan"), the 1999 Stock Option Plan (the "1999 Plan"), the 2000 Equity Incentive Plan (the "2000 Plan"), the 2001 Equity Incentive Plan (the "2001 Plan"), and the 2003 Equity Incentive Plan (the "2003 Plan," and collectively, the "Plans"). No new awards may be granted under the 1998 Plan or the 1999 Plan.

Stock options issued under the Plans become exercisable over specified periods, generally within four years from the date of grant for officers, directors and employees, and generally expire six years from the grant date for employees and from six to ten years for directors and certain executive officers. Restricted stock issued under the Plans vests over specified periods, generally three years after the date of grant. **Stock Options** 

The Company granted approximately 254,000 and 34,000 stock options during the nine months ended September 30, 2012 and September 30, 2011, respectively. As of September 30, 2012, there were approximately \$2.4 million of total unrecognized compensation costs related to unvested stock options. These costs are expected to be recognized over a

weighted-average period of approximately two years. The Company received net proceeds of \$0.7 million and \$3.5 million from stock option exercises for the nine months ended September 30, 2012 and 2011, respectively. Awards of Restricted Stock, Performance Stock and Contract Stock

Performance stock awards have performance features associated with them. Performance stock, restricted stock and contract stock awards generally have requisite service periods of three years. The Company expenses the fair value of these awards on a

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straight-line basis over the vesting period or requisite service period, whichever is shorter. The Company granted approximately 240,000 and 274,000 restricted stock awards/stock units during the nine months ended September 30, 2012 and September 30, 2011, respectively. As of September 30, 2012, there were approximately \$12.6 million of total unrecognized compensation costs related to unvested awards. The Company expects to recognize these costs over a weighted-average period of approximately two years.

The Company has no formal policy related to the repurchase of shares for the purpose of satisfying stock-based compensation obligations.

The Company also maintains an Employee Stock Purchase Plan (the "ESPP"), which provides eligible employees with the opportunity to acquire shares of common stock at periodic intervals by means of accumulated payroll deductions. The ESPP is a non-compensatory plan based on its terms.

#### 9. TREASURY STOCK

On October 29, 2010, the Company's Board of Directors authorized the Company to repurchase shares of the Company's common stock for an aggregate purchase price not to exceed \$75.0 million through December 31, 2012. Shares may be purchased either in the open market or in privately negotiated transactions.

As of September 30, 2012, there remained \$29.1 million available for repurchases under this authorization. In addition to the authorization above, on June 3, 2011, the Company's Board of Directors separately authorized the Company to repurchase shares of common stock from the proceeds of the 2016 Notes in connection with that offering. The following table sets forth the Company's treasury stock activity:

	Nine Months E	nded	Nine Months Ended September 30, 2011		
	September 30,	2012			
	\$	# of Shares	\$	# of Shares	
	(In thousands)				
Shares repurchased in the open market in connection with the Board approved buyback program	n \$—	_	\$31,441	704	
Shares repurchased in connection with the issuance of the 2016 Notes	_	_	37,570	805	
Total	_	_	\$69,011	1,509	

On October 23, 2012, the Company's Board of Directors terminated the October 2010 authorization and authorized the repurchase of up to \$75.0 million of its outstanding common stock through December 2014.

#### 10. RETIREMENT BENEFIT PLANS

The Company maintains defined benefit pension plans that cover employees in its manufacturing plants located in Andover, United Kingdom (the "UK Plan") and Tuttlingen, Germany (the "Germany Plan"). The Company closed the Tuttlingen, Germany plant in December 2005. The Company did not terminate the Germany Plan, and the Company remains obligated for the accrued pension benefits related to this plan. The plans cover certain current and former employees.

Effective March 31, 2011, the Company froze the benefits due to the participants of the UK Plan in their entirety; this curtailment resulted in a \$0.3 million reduction in the projected benefit obligations which the Company recorded on that date. The Company recorded the entire curtailment gain as an offset to the unrecognized net actuarial loss in accumulated other comprehensive income; therefore, this gain had no impact on the condensed consolidated statements of operations.

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Net periodic benefit costs for the Company's defined benefit pension plans included the following amounts:

	Three Months Ended September 30,		Nine Mon	Nine Months Ended September 30.			
	2012	2011	2012	2011			
	(In thousa	nds)					
Service cost	\$6	\$	\$19	\$53			
Interest cost	157	167	478	501			
Expected return on plan assets	(142	) (147	) (432	) (443	)		
Net period benefit cost	\$21	\$20	\$65	\$111			

The Company made \$0.6 million and \$0.9 million of contributions to its defined benefit pension plans during the nine months ended September 30, 2012 and 2011, respectively.

#### 11. INCOME TAXES

The following table provides a summary of the Company's effective tax rate:

	Three Mo	Three Months Ended September				
	30,					
	2012	2011				
Reported tax rate	7.3	% 0.4	%			
	Nine Mor	iths Ended Septem	ıber			
	30,					
	2012	2011				
Reported tax rate	19.8	% 16.7	%			

The Company expects its effective income tax rate for the full year to be approximately 20.5%. The annual effective tax rates for the periods ending in 2012 and 2011 are lower than the U.S. statutory rate of 35% due, in part, to foreign earnings taxed at lower tax rates, benefits from U.S. manufacturing incentives, tax planning and other discrete events. This estimate could be revised in the future as additional information is presented to the Company.

The Company's effective income tax rate for the three months ended September 30, 2012 and 2011 were 7.3% and 0.4%, respectively. Income tax expense for the three months ended September 30, 2012 was higher than the three month period ended September 30, 2011, as a result of a change in the mix of income reported in 2012, offset by a benefit of \$2.1 million for the release of a tax contingency reserves and a benefit of \$0.2 million change in state tax law effective this quarter. Furthermore, in this quarter, the Company settled its 2008-2010 Federal tax audit for which it recorded \$0.2 million income tax expense.

The Company's effective income tax rates for the nine months ended September 30, 2012 and 2011 were 19.8% and 16.7%, respectively. The change in year-to-date effective tax rates is attributable to the change in the mix in year-to-date worldwide pretax income, as well as a reduction in the estimated domestic manufacturing deduction, caused by a change in U.S. taxable income for 2012. The year-to-date tax increase is offset by a benefit of \$2.1 million for the release of a tax contingency reserves and a benefit of \$0.2 million for a change in state tax law effective this quarter.

Income tax expense for the nine months ended September 30, 2011 included a \$1.7 million correction to a deferred tax asset relating to 2009, and a \$0.7 million income tax expense for a state tax law change, which became effective in the quarter ended September 30, 2011.

#### 12. NET INCOME PER SHARE

Certain of the Company's restricted unvested share units contain rights to receive nonforfeitable dividends, and thus, are participating securities requiring the two-class method of computing earnings per share. The participating securities had an insignificant impact on the calculation of earnings per share (impacts the rounding by less than \$0.01 per share) on all of the 2011 periods presented; therefore, the Company does not present the full calculation below. Basic and diluted net income per share was as follows (in thousands, except per share amounts):

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	Three Months E	Ended September	Nine Months Ended September 30,		
	2012	2011	2012	2011	
Basic net income per share:					
Net income	\$13,211	\$11,243	\$28,418	\$23,429	
Weighted average common shares outstanding	28,446	28,583	28,403	29,234	
Basic net income per common share	\$0.46	\$0.39	\$1.00	\$0.80	
Diluted net income per share:					
Net income	\$13,211	\$11,243	\$28,418	\$23,429	
Weighted average common shares outstanding —	28,446	28,583	28,403	29,234	
Basic	20,440	20,303	26,403	29,234	
Effect of dilutive securities:					
Stock options and restricted stock	331	446	226	586	
Weighted average common shares for diluted earnings per share	28,777	29,029	28,629	29,820	
Diluted net income per common share	\$0.46	\$0.39	\$0.99	\$0.79	

At September 30, 2012 and 2011, the Company had 1.7 million and 1.5 million of outstanding stock options, respectively. The Company also has warrants outstanding relating to its 2016 Notes at September 30, 2012 and 2011. Stock options, restricted stock and warrants are included in the diluted earnings per share calculation using the treasury stock method, unless the effect of including the stock options would be anti-dilutive. For the three months ended September 30, 2012 and 2011, 1.0 million and 0.5 million of anti-dilutive stock options, respectively, were excluded from the diluted earnings per share calculation. For the nine months ended September 30, 2012 and 2011, 1.2 million and 0.2 million of anti-dilutive stock options, respectively, were excluded from the diluted earnings per share calculation. As the strike price of the warrants exceeded the Company's average stock price for the period, the warrants are anti-dilutive and the entire number of warrants was also excluded from the diluted earnings per share calculation.

#### 13. COMPREHENSIVE (LOSS) INCOME

Comprehensive (loss) income was as follows:

	Three Months Ended September Nine Months Ended September							ber
	30,				30,			
	2012		2011		2012		2011	
	(In thousands	s)						
Net Income	\$13,211		\$11,243		\$28,418		\$23,429	
Foreign currency translation adjustment	4,051		(17,712	)	(106	)	688	
Change in unrealized gain on derivatives, net of tax	(154	)	(1,439	)	(290	)	(2,372	)
Pension liability adjustment, net of tax	(2	)	14		(6	)	200	
Comprehensive income (loss)	\$17,106		\$(7,894	)	\$28,016		\$21,945	

#### 14. SEGMENT AND GEOGRAPHIC INFORMATION

Starting in the first quarter of 2012, because of changes in how the Company internally manages and reports the results of its businesses to its chief operating decision maker, the Company began to disclose five reportable segments. The five reportable segments are U.S. Neurosurgery, U.S. Instruments, U.S. Extremities, U.S. Spine and Other, and International. The U.S. Neurosurgery segment sells a full line of products specifically for neurosurgery and critical care such as tissue ablation equipment, dural repair products, cerebral spinal fluid management devices, intracranial monitoring equipment, and cranial stabilization equipment. The U.S. Instruments business sells more than 60,000 instrument patterns and surgical products and lighting to hospitals, surgery centers, and dental, podiatry, and

veterinary offices. The U.S. Extremities segment includes the U.S. extremity reconstruction business, which includes such offerings as skin and wound repair, bone and joint fixation, implants in the upper and lower extremities, bone grafts and nerve and tendon repair. The U.S. Spine and Other segment includes (i) the U.S. Spine business, which focuses on spinal fusion, spinal implants, and deformity correction, (ii) the U.S. Orthobiologics business, which focuses on bone graft substitutes and other related medical devices that are used to enhance the repair and regeneration of bone in various types of orthopedic surgical procedures, and (iii) the Private Label business, which sells the Company's regenerative medicine and other products to strategic partners. The International segment sells similar products to those discussed above, but are managed through the following geographies: (i) Europe, Middle East and Africa, and (ii) Central/South America, Asia-Pacific and Canada. The Corporate and other category includes (i) various legal, finance,

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executive, and human resource functions, (ii) brand management, (iii) share-based compensation costs, and (iv) costs related to procurement, manufacturing operations and logistics for the Company's entire organization. Accordingly, the segment information for the prior years has been restated in accordance with authoritative guidance on segment reporting.

The operating results of the various reportable segments as presented are not comparable to one another because (i) certain operating segments are more dependent than others on corporate functions for unallocated general and administrative and/or operational manufacturing functions, and (ii) the Company does not allocate certain manufacturing costs and general and administrative costs to the operating segment results.

Net sales and profit by reportable segment for the three and nine months ended September 30, 2012 and 2011 are as follows:

	Three Months End	ed September	Nine Months Ended September 30,				
	30,		Time Months Ended	a september 50,			
	2012	2011	2012	2011			
	(In thousands)						
Segment Net Sales							
U.S. Neurosurgery	\$43,269	\$42,800	\$125,776	\$122,246			
U.S. Instruments	41,469	41,543	120,732	116,932			
U.S. Extremities	32,961	24,825	91,596	69,341			
U.S. Spine and Other	49,188	48,293	142,821	128,885			
International	43,197	44,724	135,514	139,151			
Total revenues	\$210,084	\$202,185	\$616,439	\$576,555			
Segment Profit							
U.S. Neurosurgery	\$23,201	\$22,624	\$66,247	\$62,489			
U.S. Instruments	9,293	8,779	26,259	22,029			
U.S. Extremities	14,996	9,657	37,484	27,692			
U.S. Spine and Other	14,771	13,390	42,166	38,576			
International	14,550	14,721	45,456	48,911			
Segment profit	76,811	69,171	217,612	199,697			
Amortization	(4,618)	(4,548)	(13,985)	(11,609)			
Corporate and other	(52,457)	(46,332)	(148,403)	(140,925)			
Operating income	\$19,736	\$18,291	\$55,224	\$47,163			

The segment profits for the U.S. Instruments and U.S. Extremities segments for the three months ended March 31, 2012 and 2011 have been revised and are reflected in the segment profits for the nine months ended September 30, 2012 and 2011.

Revenue by major product category consisted of the following:

	Three Months	Nine Months Ended September				
	30,			30,		
	2012	2011	2012	2011		
	(In thousands)					
Orthopedics	\$94,186	\$85,698	\$276,033	\$239,429		
Neurosurgery	69,667	69,768	203,499	203,129		
Instruments	46,231	46,719	136,907	133,997		
Total Revenues	\$210,084	\$202,185	\$616,439	\$576,555		

The Company attributes revenues to geographic areas based on the location of the customer. There are certain revenues that the various U.S. segments manage that are generated from non-U.S. customers and therefore included in Europe and the Rest of World revenues below. Total revenue by major geographic area consisted of the following:

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	Three Month	s Ended Septemb	er Nine Months	Nine Months Ended September		
	30,		30,	30,		
	2012	2011	2012	2011		
	(In thousands	s)				
United States	\$165,930	\$156,530	\$478,087	\$434,324		
Europe	20,351	21,839	66,903	72,203		
Rest of World	23,803	23,816	71,449	70,028		
Total Revenues	\$210,084	\$202,185	\$616,439	\$576,555		

#### 15. COMMITMENTS AND CONTINGENCIES

In consideration for certain technology, manufacturing, distribution, and selling rights and licenses granted to the Company, the Company has agreed to pay royalties on sales of certain products that we sell. The royalty payments that the Company made under these agreements were not significant for any of the periods presented.

The Company is subject to various claims, lawsuits and proceedings in the ordinary course of its business, including claims by current or former employees, distributors and competitors in respect to its products. In the opinion of management, such claims are either adequately covered by insurance or otherwise indemnified, or are not expected, individually or in the aggregate, to result in a material adverse effect on the Company's financial condition. However, it is possible that these contingencies could materially affect its results of operations, financial position and cash flows in a particular period.

The Company has settled, or has pending against it, various lawsuits, claims and proceedings. The Company accrues for loss contingencies when it is deemed probable that a loss has been incurred and that loss is estimable. The amounts accrued are based on the full amount of the estimated loss before considering insurance proceeds, and do not include an estimate for legal fees expected to be incurred in connection with the loss contingency. The Company consistently accrues legal fees expected to be incurred in connection with loss contingencies as a period cost as outside counsel incurs those fees.

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# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes thereto appearing elsewhere in this report and our consolidated financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K.

We have made statements in this report which constitute 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 (the "Exchange Act"). These forward-looking statements are subject to a number of risks, uncertainties and assumptions about the Company. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth above under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011 and under the heading "Risk Factors" in this Report. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

You can identify these forward-looking statements by forward-looking words such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," "would" and similar expressions in this repo

#### **GENERAL**

Integra is a world leader in medical devices focused on limiting uncertainty for surgeons so they can concentrate on providing the best patient care. Integra provides customers with clinically relevant, innovative and cost-effective products that improve the quality of life for patients. We focus on cranial and spinal procedures, small bone and joint injuries, the repair and reconstruction of soft tissue, and instruments for surgery.

We manage our business through a combination of product groups and geography, and accordingly, we report our financial results under five reportable segments - U.S. Instruments, U.S. Neurosurgery, U.S. Extremities, U.S. Spine and Other (which consists of our U.S. Spine, U.S. Orthobiologics and Private Label businesses) and International. We present revenues in the following three product categories: Orthopedics, Neurosurgery and Instruments. Our orthopedics products group includes specialty metal implants for surgery of the extremities, shoulder and spine, orthobiologics products for repair and grafting of bone, dermal regeneration products and tissue-engineered wound dressings and nerve and tendon repair products. Our neurosurgery products group includes, among other things, dural grafts that are indicated for the repair of the dura mater, ultrasonic surgery systems for tissue ablation, cranial stabilization and brain retraction systems, systems for measurement of various brain parameters and devices used to gain access to the cranial cavity and to drain excess cerebrospinal fluid from the ventricles of the brain. Our instruments products group includes a wide range of specialty and general surgical and dental instruments and surgical lighting for sale to hospitals, outpatient surgery centers, and physician, veterinarian and dental practices.

We manufacture many of our products in plants located in the United States, Puerto Rico, France, Germany, Ireland, the United Vinedom and Maxima We also source meet of our hondeld surgical instruments and general and

We manufacture many of our products in plants located in the United States, Puerto Rico, France, Germany, Ireland, the United Kingdom and Mexico. We also source most of our handheld surgical instruments and specialty metal and Pyrocarbon implants through specialized third-party vendors.

In the United States, we have several sales channels. Orthopedics products are sold through a large direct sales organization and through specialty distributors focused on their respective surgical specialties. Neurosurgery products are sold through directly employed sales representatives. Instruments products are sold through two sales channels, both directly and through distributors and wholesalers, depending on the customer call point. We sell in the international markets through a combination of a direct sales organization and specialty distributors.

We also market certain products through strategic partners in the United States.

Our objective is to become a diversified global medical device company that helps patients by limiting uncertainty for medical professionals, and to be a high-quality investment for shareholders. We will achieve these goals by delivering on our Brand Promises to our customers worldwide and by becoming a top player in all markets in which we compete. Our strategy includes the following key elements: geographic expansion, margin expansion, leveraging platform synergies, disciplined focus and execution, global quality assurance and acquiring or in-licensing products that fit existing sales channels.

We aim to achieve growth in our revenues while maintaining strong financial results. While we pay attention to any meaningful trend in our financial results, we pay particular attention to measurements that are indicative of long-term profitable growth. These measurements include (1) revenue growth (including internal growth and by acquisitions), (2) gross margins on total revenues, (3) operating margins (which we aim to continually expand as we leverage our existing infrastructure), (4) earnings

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before interest, taxes, depreciation, and amortization, and (5) earnings per diluted share of common stock.

We believe that we are particularly effective in the following aspects of our business:

Regenerative Medicine Platform. We have developed numerous product lines through our proprietary collagen matrix and demineralized bone matrix technologies that are sold through every one of our sales channels.

Diversification and Platform Synergies. Each of our three selling platforms contributes a different strength to our core business. Orthopedics enables us to grow our top line and increase gross margins. Neurosurgery provides stable growth as a market with few elective procedures. Instruments has a strong capacity to generate cash flows. We have unique synergies among these platforms, such as our regenerative medicine technology, instrument sourcing capabilities, and Group Purchasing Organization ("GPO") contract management.

Unique Sales Footprint, Our sales footprint provides us with a unique set of customer call-points and synergies, Each of our sales channels can benefit from the GPO and Integrated Delivery Network ("IDN") relationships that our Instruments group manages. We have market leading products among neurosurgeons, many of whom also perform spine surgeries, and we have yet to fully leverage those relationships to sell our spine products. We also have clinical expertise across all of our channels in the United States, and have an opportunity to expand and leverage this expertise in markets worldwide.

Ability to Change and Adapt. Our corporate culture is truly what enables us to adapt and reinvent ourselves. We have demonstrated that we can quickly and profitably integrate new products and businesses. This core strength has made it possible for us to grow over the years, and is key to our ability to grow into a multi-billion dollar company.

#### **RESULTS OF OPERATIONS**

**Executive Summary** 

Net income for the three months ended September 30, 2012 was \$13.2 million, or \$0.46 per diluted share as compared with net income of \$11.2 million or \$0.39 per diluted share for the three months ended September 30, 2011. Net income for the nine months ended September 30, 2012 was \$28.4 million, or \$0.99 per diluted share as compared with net income of \$23.4 million or \$0.79 per diluted share for the nine months ended September 30, 2011. The increase in net income for the three months ended September 30, 2012 over the same period last year resulted primarily from higher revenues, higher gross margin on our revenues, and a decrease in our interest expense as a result of the June 2012 repayment of our 2012 Notes.

The increase in net income for the nine months ended September 30, 2012 over the same period last year resulted primarily from an increase in revenue from the addition of SeaSpine and Ascension's existing products and the margin contribution from those higher revenues. The prior year period included \$8.4 million of incremental stock based compensation charges related to our former chief executive officer's employment agreement. Our costs and expenses include the following charges:

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	Three Months Ended		Nine Months Ended Septer	
	September 30,		30,	
	2012	2011	2012	2011
	(In thousands)		(In thousands)	
Plainsboro, New Jersey manufacturing facility remediation costs	\$3,788	1,748	\$7,193	1,748
Global ERP implementation charges	4,821	6,245	12,097	11,832
Facility optimization charges	2,861	34	7,481	2,127
Certain employee termination charges	638	_	1,139	846
Discontinued product lines charges	223	485	1,058	3,664
Acquisition-related charges	602	1,665	2,323	4,227
Impairment charges	_	_	141	2,648
European entity restructuring charges	_	_		378
Convertible debt non-cash interest	1,787	3,417	8,284	7,049
Certain executive compensation charges	_	100		8,479
Financing charges	_	_		790
Total	\$14,720	\$13,694	\$39,716	\$43,788

The items reported above are reflected in the condensed consolidated statements of operations as follows:

	Three Months Ended		Nine Months Ended Septe	
	September 30,		30,	
	2012	2011	2012	2011
	(In thousands)		(In thousands)	
Cost of goods sold	\$5,661	\$3,518	\$13,890	\$8,372
Research and development		_		300
Selling, general and administrative	7,272	6,759	17,542	26,129
Intangible asset amortization				1,148
Interest expense	1,787	3,417	8,284	7,839
Total	\$14,720	\$13,694	\$39,716	\$43,788

We typically define special charges as items for which the amounts and/or timing of such expenses may vary significantly from period to period, depending upon our acquisition, integration and restructuring activities, and for which the amounts are non-cash in nature, or for which the amounts are not expected to recur at the same magnitude as we implement certain tax planning strategies. We believe that given our ongoing strategy of seeking acquisitions, our continuing focus on rationalizing our existing manufacturing and distribution infrastructure and our continuing review of various product lines in relation to our current business strategy, certain of the special charges discussed above could recur with similar materiality in the future. In 2010 we began investing significant resources in the global implementation of a single enterprise resource planning system. We began capitalizing certain costs for the project starting in 2011, and as other aspects of the project reach the application development stage, we will capitalize those expenditures as well.

We believe that the separate identification of these special charges provides important supplemental information to investors regarding financial and business trends relating to our financial condition and results of operations. Investors may find this information useful in assessing comparability of our operating performance from period to period, the business model objectives that management has established, and other companies in our industry. We provide this information to investors so that they can analyze our operating results in the same way that management does and to use this information in their assessment of our core business and valuation of Integra.

Plainsboro, New Jersey Regenerative Medicine Facility Update

Remediation activities in our regenerative medicine facility in Plainsboro, New Jersey affected revenues and gross margin in the third quarter and first nine months of 2012. We received a warning letter from the FDA in December 2011, related to quality systems and compliance issues at that plant. The letter resulted from an inspection held at that facility in August 2011, and did not identify any new observations that were not provided in the Form 483 that followed the inspection. The warning letter did not restrict our ability to manufacture or ship products, nor did it require the recall of any product. In July 2012, the FDA again

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inspected the regenerative medicine facility; the second inspection closed out on July 30, 2012 and a FDA Form 483 Inspectional Observations was issued. We have been addressing the FDA 483 Inspectional Observations, Warning Letter citations and communicating with the FDA on a monthly basis. Our efforts with respect to closing out the warning letter are well along, and we do not expect the FDA to return for another inspection until late 2012 or in 2013. See Part II - Item 1A. Risk Factors for more detailed discussion.

Since August 2011, we have undertaken significant efforts to remediate the observations that the FDA has made and continue to do so, including both capital investment for new equipment, leasehold improvements and incremental spending to improve or revise quality systems. We expensed approximately \$3.8 million and \$7.2 million in the three and nine months of 2012, respectively. For the three month period, the \$3.8 million consisted of \$0.4 million of expenses associated with remediation of the Plainsboro, New Jersey collagen device facility and \$3.4 million for unplanned idle time and underutilization. For the nine month period, the \$7.2 million consisted of \$2.5 million of expenses associated with remediation of the Plainsboro, New Jersey collagen device facility and \$4.7 million for unplanned idle time and underutilization. The capital expenditure directed to the remediation of our regenerative medicine facility was \$2.8 and \$4.9 million for the three and nine months ended September 30, 2012, respectively. We anticipate spending another \$0.5 million including underutilization over the remainder of the year.

Revenues and Gross Margin on Product Revenues

Our revenues and gross margin on product revenues were as follows:

	Three Months E	Ended September	Nine Months Er	ided September
	30,		30,	
	2012	2011	2012	2011
	(In thousands)		(In thousands)	
Orthopedics	\$94,186	\$85,698	\$276,033	\$239,429
Neurosurgery	69,667	69,768	203,499	203,129
Instruments	46,231	46,719	136,907	133,997
Total revenue	210,084	202,185	616,439	576,555
Cost of goods sold	79,548	78,651	232,497	216,410
Gross margin on total revenues	\$130,536	\$123,534	\$383,942	\$360,145
Gross margin as a percentage of total revenues	62.1 %	61.1 %	62.3 %	62.5 %
Net Revenues by Reportable Segment				

Net sales by reportable segment for the three and nine months ended September 30, 2012 and 2011 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousand	ls)	(In thousand	ds)
Segment Net Sales				
U.S. Neurosurgery	43,269	42,800	125,776	122,246
U.S. Instruments	41,469	41,543	120,732	116,932
U.S. Extremities	32,961	24,825	91,596	69,341
U.S. Spine and Other	49,188	48,293	142,821	128,885
International	43,197	44,724	135,514	139,151
Total revenues	210,084	202,185	616,439	576,555

Three Months Ended September 30, 2012 as Compared to Three Months Ended September 30, 2011 Revenues and Gross Margin

For the three months ended September 30, 2012, total revenues increased by \$7.9 million, or 4%, to \$210.1 million from \$202.2 million for the same period during 2011. Domestic revenues increased 6% to \$165.9 million, or 79% of total revenues, for the three months ended September 30, 2012 from \$156.5 million, or 77% of total revenues, for the three months ended

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September 30, 2011. International revenues decreased to \$44.2 million from \$45.7 million in the prior-year period, a decrease of 3%, driven in part by foreign exchange fluctuations from a weaker euro versus the U.S. dollar compared to the third quarter of 2011. Overall foreign exchange rate fluctuations accounted for a \$2.5 million decrease in revenues during the third quarter of 2012 as compared to the same period last year. Finally, total revenues were negatively impacted by various supply disruptions, none of which were material individually, resulting in a larger than usual total backorder at the end of the quarter. The Company expects to resolve most of these disruptions by the end of 2012, but there can be no assurance that backorder levels will return to normal.

- U.S. Neurosurgery revenues were \$43.3 million, an increase of 1% from the prior year. The increase was due to stronger sales of our duraplasty and specialty products offset by softer capital sales in cranial fixation.
- U.S. Instruments revenues were \$41.5 million, in line with the prior year. We continued to experience strong sales within instruments, largely driven by strength in our acute care sales channel, and continued growth of our LED surgical headlamp product, which was launched in late 2011. Our strong growth was offset by the timing of alternate site channel that experienced a significant spike in sales in the third quarter of 2011.
- U.S. Extremities revenues were \$33.0 million, an increase of 33% from the prior year. The growth resulted primarily from significant increases in sales of our dermal and wound care products and Ascension products. We are still experiencing some backorders that resulted from the remediation work in our Plainsboro, New Jersey manufacturing facility, which delayed production of regenerative medicine products.
- U.S. Spine and Other revenues, which include our Spine hardware, orthobiologics and private label products, were \$49.2 million, an increase of 2% from the prior year. We continued double digit growth in our orthobiologics business, led by a strong demand for our EVO3 and Mozaik products. Our sales team has been focused on signing up new distributors and as a result we have seen increases in sales of our products. Our Spine hardware products business has experienced some price erosion because of increasing competition. Increased spine procedure delays have also affected demand for our products. Sales of our private label products increased from the prior year.

International segment revenues were \$43.2 million, down 3% from the prior year. We experienced a negative foreign currency impact of \$2.5 million, which primarily affected our sales in Europe. With constant currency rates, Europe would have increased approximately 4%. In addition, we saw decreases in capital spending, as European hospitals have been reducing spending and tightening their budgets. Increases in skin and wound-healing product sales partially offset these decreases. We also saw revenue increases in the Asia-Pacific and Latin America markets across all product categories.

Gross margin increased 6% to \$130.5 million for the three-month period ended September 30, 2012 from \$123.5 million for the same period last year. Gross margin as a percentage of total revenue increased slightly to 62.1% for the third quarter 2012 from 61.1% for the same period last year. The increase in gross margin percentage resulted primarily from a decrease in our inventory reserves.

We expect our consolidated gross margin percentage for the full year 2012 to be flat to up slightly compared to 2011. We expect to complete the remediation work at our Plainsboro, New Jersey regenerative medicine manufacturing facility in the fourth quarter of 2012 and accordingly, expect to return to normal levels of production during the fourth quarter of 2012. That said, higher costs resulting from the amortization of the Ascension and SeaSpine inventory to cost of goods sold at acquisition value, costs related to the expansion of our regenerative medicine activities, and continued downward pressure on our private-label and spine hardware product sales volumes will negatively affect our consolidated gross margin.

**Operating Expenses** 

The following is a summary of operating expenses as a percent of total revenues:

	Three Months Ended September			
	30,			
	2012	2011		
Research and development	6.2	% 6.6	%	
Selling, general and administrative	44.3	% 43.3	%	
Intangible asset amortization	2.2	% 2.2	%	

Total operating expenses

52.7

% 52.1

%

Total operating expenses, which consist of research and development expenses, selling, general and administrative expenses and amortization expense, increased \$5.6 million, or 5%, to \$110.8 million in the three months of 2012, compared to \$105.2

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million in the same period last year.

Research and development expenses in the third quarter of 2012 remained relatively flat compared to the same period last year. We target full-year 2012 spending on research and development to be between 6% and 6.5% of total revenues.

Selling, general and administrative expenses in the third quarter of 2012 increased by \$5.6 million to \$93.1 million compared to \$87.5 million in the same period last year. Selling and marketing expenses increased by \$2.9 million, primarily resulting from a higher proportion of sales through distributors, which generally have a higher cost than the direct selling model. Additionally, bonuses and commission costs were higher as a result of increases in revenue. General and administrative costs were up \$2.7 million, primarily because of an increase in accrued non-selling bonuses and consulting costs to support various strategic projects. These increases were somewhat offset by lower costs in our European operations resulting from lower headcount and severance costs paid in third quarter 2011. Amortization expense in the third quarter of 2012 was \$4.6 million compared to \$4.5 million in the same period last year. The increase primarily resulted from amortization of the significant intangible assets added as part of our Ascension acquisition that occurred during the third quarter of 2011.

Non-Operating Income and Expenses

The following is a summary of non-operating income and expenses:

	Three Months Ended September 30,		
	2012	2011	
	(In thousand	ls)	
Interest income	\$100	\$154	
Interest expense	(5,549	) (7,587	)
Other income (expense)	(31	) 429	

### Interest Income and Interest Expense

Interest expense in the three months ended September 30, 2012 decreased primarily as a result of the June repayment of our 2012 Notes which decreased our interest expense by \$2.9 million, offset by an additional \$0.8 million of higher interest because of increased borrowing on our revolver. Our reported interest expense for the three-month periods ended September 30, 2012 and 2011 includes non-cash interest related to the accounting for convertible securities of \$1.8 million and \$3.4 million, respectively.

Other Income (Expense)

Other expense for the third quarter of 2012 was primarily attributable to foreign exchange gains and losses on intercompany balances.

Other income for the third quarter of 2011 of \$0.4 million consists primarily of foreign exchange gains on intercompany balances.

**Income Taxes** 

	Three Month	ree Months Ended September 30,		
	2012	2011		
	(In thousands	s)		
Income before income taxes	14,256	11,287		
Income tax expense	1,045	44		
Effective tax rate	7.3	% 0.4	%	

Our effective income tax rate for the three months ended September 30, 2012 and 2011 were 7.3% and 0.4%, respectively. Income tax expense for the three months ended September 30, 2012 was higher than the three-month period ended September 30, 2011, as a result of a change in the mix of income reported in 2012, offset by a benefit of

\$2.1 million for the release of a tax contingency reserve and a benefit of \$0.2 million change in state tax law effective this quarter. Furthermore, in this quarter, the Company settled its 2008-2010 Federal tax audit for which it recorded \$0.2 million income tax expense.

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The effective tax rate may vary from period to period depending on, among other factors, the geographic and business mix of taxable earnings and losses, tax planning and settlements with the various taxing authorities. We consider these factors and others, including our history of generating taxable earnings, in assessing our ability to realize deferred tax assets on a quarterly basis.

While it is often difficult to predict the final outcome or the timing of resolution of any particular matter with the various Federal, state and foreign tax authorities, we believe that our reserves reflect the most probable outcome of known tax contingencies. Settlement of any particular issue would usually require the use of cash. Favorable resolution would be recognized as a reduction to our annual effective tax rate in the year of resolution. The tax reserves are presented in the balance sheet within other liabilities, except for amounts relating to items we expect to pay in the coming year which are classified as current income taxes payable.

We expect our effective income tax rate for the full year to be approximately 20.5%.

Nine Months Ended September 30, 2012 as Compared to Nine Months Ended September 30, 2011

### Revenues and Gross Margin

For the nine-month period ended September 30, 2012, total revenues increased by \$39.9 million or 7%, to \$616.4 million from \$576.6 million during the prior-year period. Domestic revenues increased by 10% to \$478.1 million, and were 78% and 75% of total revenues for the nine months ended September 30, 2012 and 2011, respectively. International revenues decreased by 3% to \$138.4 million, driven by foreign exchange fluctuation from a weaker euro versus the U.S. dollar compared to the same period last year. Overall foreign exchange rate fluctuations accounted for a \$6.1 million decrease in revenues during the nine month period ended September 30, 2012 as compared to the same period last year.

- U.S. Neurosurgery revenues were \$125.8 million, an increase of 3% from the prior year. The increase in sales was from continued and growing demand for our market-leading duraplasty products, increases in sales of our ultrasonic tissue ablation systems, as well as strength in our critical care, stereotaxy and cranial stabilization products. We experienced a strong performance in both our capital equipment and disposable products.
- U.S. Instruments revenues were \$120.7 million, an increase of 3% from the prior year period. Strength in our acute care sales channel largely drove this growth. We also continue to experience strong growth of our LED surgical headlamp product, which was launched in late 2011, as well as growth in our market share. A solid amount of new facility openings have created more selling opportunities, also contributing to this growth.
- U.S. Extremities revenues were \$91.6 million, an increase of 32% from the prior year. This increase in revenue is derived from the impact of our Ascension acquisition in the third quarter of 2011. Our direct sales force began selling the full line of Ascension's portfolio of products in early 2012, moving us away from the legacy distributor network. Increases also occurred in dermal and wound care products as the demand for the products continue to be strong. We cleared most, but not all of the backorders caused by shortages of our regenerative medicine products that resulted from remediation work in our Plainsboro, New Jersey facility.
- U.S. Spine and Other revenues, which include our spine hardware, orthobiologics and private label products, were \$142.8 million, an increase of 11% from the prior year. The increase arose primarily because of the addition of SeaSpine's revenue and strong growth in our orthobiologics portfolio. Our EVO3 and Mozaik products continue to see high demand through both our existing base and newly added distributors, which are driving double-digit growth for orthobiologics during the period. While the new product launches, new distributor on-boarding and cross-pollination of the two spine hardware lines is progressing well, the spine hardware market remains challenging, both in price and volume. Private label decreased versus the prior-year period.

International segment revenues were \$135.5 million, a decrease of 3% from prior year. The current financial situation in Europe has caused hospitals to tighten their budgets. As a result, we saw decreases in capital spending on neurosurgical equipment and purchases of extremity products. These declines were partially offset by our spine and orthobiologics sales, which have increased off a relatively small base in 2011. The shortages of our regenerative medicine products discussed above also affected sales outside the United States. That said, during the second quarter

we began our delivery of skin products that had been backordered. We experienced slight increases in the Asia-Pacific and Latin America markets across all product categories.

Gross margin increased 7% to \$383.9 million for the nine-month period ended September 30, 2012. Gross margin as a percentage of total revenue decreased to 62.3% for the first nine months of 2012 from 62.5% for the same period last year. The decrease in gross margin percentage primarily resulted from our ongoing remediation efforts in our Plainsboro, New Jersey

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manufacturing facility. In addition, we discontinued our radiosurgery and radiotherapy product lines and wrote-off the related technology intangible assets and inventory, which resulted in \$1.0 million of incremental costs during the first quarter. Finally, we incurred additional costs related to the amortization of the fair value inventory step-up on the acquired SeaSpine and Ascension inventories from 2011.

**Operating Expenses** 

The following is a summary of operating expenses as a percent of total revenues:

	Nine Months Ended September 30,		
	2012	2011	
Research and development	6.2	% 6.6	%
Selling, general and administrative	44.9	% 45.7	%
Intangible asset amortization	2.3	% 2.0	%
Total operating expenses	53.4	% 54.3	%

Total operating expenses, which consist of research and development expenses, selling, general and administrative expenses and amortization expense, increased \$15.7 million, or 5%, to \$328.7 million in the nine months of 2012, compared to \$313.0 million in the same period last year.

Research and development expenses in the first nine months of 2012 remained flat, compared to the same period last year. Product development efforts for our spine and extremity reconstruction product lines were offset by lower spending in neurosurgery and instrument product development activities. We target full-year 2012 spending on research and development to be between 6% and 7% of total revenue.

Selling, general and administrative expenses in the nine months of 2012 increased by \$13.3 million to \$276.6 million compared to \$263.3 million in the same period last year. Selling and marketing expenses increased by \$19.0 million primarily resulting from a higher proportion of sales to distributors, which inherently have a higher cost than the direct selling model together with increases in revenue and corresponding commission costs, as well as the impact of our SeaSpine and Ascension acquisitions. Additionally, we incurred \$1.1 million of expenses in the second quarter to terminate an exclusive product distribution agreement with a former distributor in China, which included the transfer of certain product registration rights back to us. General and administrative costs decreased \$5.7 million primarily due to prior year incremental charges of \$8.4 million of stock based compensation related to the renewal of our former chief executive officer's employment agreement and \$2.0 million of acquisition related costs that did not repeat in the current period. These decreases were offset by increases in accrued non-selling bonuses, consulting and other costs related to various strategic projects and the addition of our SeaSpine and Ascension operations.

Amortization expense in the first nine months of 2012 increased by \$2.4 million to \$14.0 million compared to \$11.6 million in the same period last year. The increase was primarily related to amortization of the significant intangible assets added as part of our Ascension acquisition that occurred during the third quarter of 2011 and accelerated amortization on several trade names being phased out as part of our rebranding strategy.

Non-Operating Income and Expenses

The following is a summary of non-operating income and expenses:

	Nine Months Ended September 30,		
	2012	2011	
	(In thousands	s)	
Interest income	\$893	\$354	
Interest expense	(20,581	) (19,778	)
Other income (expense)	(118	) 379	

Interest Income and Interest Expense

Interest income increased in the nine-month period ended September 30, 2012, compared to the same period last year, primarily

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from short-term investments in time deposit accounts held outside the United States.

Interest expense in the nine-month period ended September 30, 2012 increased primarily as a result of increased borrowing on our revolver. Our reported interest expense for the nine-month periods ended September 30, 2012 and 2011 includes non-cash interest related to the accounting for convertible securities of \$8.3 million and \$7.1 million, respectively.

Other Income (Expense)

Other expenses of \$0.1 million in 2012 were primarily attributable to foreign exchange gains and losses on intercompany balances. Other income (expense) in the nine months ended September 30, 2011 consisted of research and development reimbursements from third-party partners and foreign governments, which was almost entirely offset by foreign exchange losses.

Income Taxes

	Nine Months Ended September 30,			
	2012		2011	
	(In thousands)			
Income before income taxes	35,418		28,118	
Income tax expense	7,000		4,689	
Effective tax rate	19.8	%	16.7	%

The Company's effective income tax rates for the nine months ended September 30, 2012 and 2011 were 19.8% and 16.7%, respectively. The change in year-to-date effective tax rates is attributable to the change in the mix in year-to-date worldwide pretax income, as well as a reduction in the estimated domestic manufacturing deduction, caused by a change in U.S. taxable income for 2012. The year-to-date tax increase is offset by a benefit of \$2.1 million for the release of a tax contingency reserves and a benefit of \$0.2 million for a change in state tax law effective this quarter.

Income tax expense for the nine months ended September 30, 2011 included a \$1.7 million correction to a deferred tax asset relating to 2009, and a \$0.7 million income tax expense for a tax law change, which became effective in the quarter ended September 30, 2011.

The effective tax rate may vary from period to period depending on, among other factors, the geographic and business mix of taxable earnings and losses, tax planning and settlements with the various taxing authorities. We consider these factors and others, including our history of generating taxable earnings, in assessing our ability to realize deferred tax assets on a quarterly basis.

While it is often difficult to predict the final outcome or the timing of resolution of any particular matter with the various Federal, state and foreign tax authorities, we believe that our reserves reflect the most probable outcome of known tax contingencies. Settlement of any particular issue would usually require the use of cash. Favorable resolution would be recognized as a reduction to our annual effective tax rate in the year of resolution. The tax reserves are presented in the balance sheet within other liabilities, except for amounts relating to items it expects to pay in the coming year which are classified as current income taxes payable.

We expect our effective income tax rate for the full year to be approximately 20.5%.

# GEOGRAPHIC PRODUCT REVENUES AND OPERATIONS

We attribute revenues to geographic areas based on the location of the customer. There are certain revenues that the various U.S. segments manage that are generated from non-U.S. customers and therefore included in Europe and the Rest of World revenues below – these revenues are not significant. Total revenue by major geographic area consisted of the following:

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	Three Months Ended September			Nine Months Ended September		
	30,		30,			
	2012	2011	2012	2011		
	(in thousands	s)	(in thousands	s)		
United States	\$165,930	\$156,530	\$478,087	\$434,324		
Europe	20,351	21,839	66,903	72,203		
Rest of World	23,803	23,816	71,449	70,028		
Total Revenues	\$210,084	\$202,185	\$616,439	\$576,555		

For more detailed view of revenue fluctuations see our discussion of international revenues under the Item 2 section titled Results of Operations – "Revenues and Gross Margins."

We generate significant revenues outside the United States, a portion of which are U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. As a result, currency fluctuations between the U.S. dollar and the currencies in which those customers do business could have an impact on the demand for our products in foreign countries.

Local economic conditions, regulatory compliance or political considerations, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice all may combine to affect our sales into markets outside the United States.

### LIQUIDITY AND CAPITAL RESOURCES

Cash and Marketable Securities

We had cash and cash equivalents totaling approximately \$125.7 million and \$100.8 million at September 30, 2012 and December 31, 2011, respectively. At September 30, 2012, our non-U.S. subsidiaries held approximately \$113.5 million of cash and cash equivalents that are available for use by all of our operations outside of the United States. If these funds were repatriated to the United States, or used for United States operations, certain amounts could be subject to tax in the United States for the incremental amount in excess of the foreign tax paid.

Cash Flows

	Nine Months Ended September 30,			
	2012	2011		
	(In thousands)			
Net cash provided by operating activities	\$62,503	\$69,633		
Net cash used in investing activities	(49,503	) (174,801	)	
Net cash provided by (used in) financing activities	8,933	87,244		
Effect of exchange rate fluctuations on cash	2,977	152		
Net increase (decrease) in cash and cash equivalents	\$24,910	\$(17,772	)	

In the second quarter of 2012, we borrowed \$155 million from our senior credit facility to fund the June repayment of our 2012 Notes of \$165 million, of which we classified \$134 million as a financing use of cash for the repayment of the debt component, and \$31 million as an operating use of cash for the repayment of accreted interest. We plan to spend approximately \$20 million on capital expenditures in the last quarter of 2012, primarily for the expansion of regenerative medicine manufacturing capacity, our enterprise resource planning system implementation, and additions to our instrument sets used in sales of orthopedic products.

In the fourth quarter, the Company will use cash to pay withheld federal and state taxes in connection with the release to Mr. Essig of approximately 1.67 million deferred stock units ("SUs") as a result of the termination of his employment. On June 7, 2012, our executive chairman ceased to be an employee of the Company. Mr. Essig continues to serve as Chairman and as a member of the Board of Directors. These SUs will be distributed to him in the form of shares of our common stock within approximately six months after the date he ceased to be an employee of the Company. Most of the payments will be classified as an operating use of cash. Accordingly, the SUs will be

distributed and taxes will be withheld in the fourth quarter of 2012. The Company will retain shares equal in value to the required withholding taxes, which may exceed 44% of the then aggregate fair market value of the SUs. The Company will be able to deduct the total amount of such deferred compensation from its

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Federal and state corporation taxes, but will not receive the cash benefits of such deductions in the same period. The payment of the SUs in the current year will generate net operating losses for the Company which will be utilized as deductions against federal and state corporate income taxes over the next two years.

## Cash Flows Provided by Operating Activities

We generated operating cash flows of \$62.5 million and \$69.6 million for the nine months ended September 30, 2012 and 2011, respectively.

Operating cash flows were lower than the same period in 2011 largely because of the repayment of our convertible 2012 Notes of \$165 million, of which \$31.0 million we classified as an operating use of cash for the repayment of accreted interest. Net income for the nine months ended September 30, 2012, plus items included in those earnings that did not result in a change to our cash balance, amounted to approximately \$51.1 million. Changes in working capital increased cash flows by approximately \$13.5 million. Among the changes in working capital, accounts receivable used \$1.3 million of cash, inventory provided \$1.1 million of cash, prepaid expenses and other current assets provided \$8.1 million of cash, and accounts payable, accrued expenses and other current liabilities provided \$6.5 million of cash.

### Cash Flows Used in Investing Activities

During the nine months ended September 30, 2012, we paid \$44.4 million in cash for capital expenditures, most of which was directed to the expansion of our regenerative medicine production capacity and global enterprise system implementation. We had net purchases of \$3.0 million in short-term time deposit accounts which is the impact of changes in foreign exchange rates.

During the nine months ended September 30, 2011, we paid \$149.4 million (net of \$0.8 million of cash acquired) related to our acquisitions of Ascension Orthopedics, Inc. and SeaSpine, Inc. and incurred \$25.4 million in capital expenditures related primarily to expanding our regenerative medicine manufacturing capacity and to the implementation of our global enterprise resource planning system.

### Cash Flows Provided by Financing Activities

Our principal uses of cash for financing activities in the nine months ended September 30, 2012 were \$155.0 million of borrowings under our Senior Credit Facility offset by the repayment of the liability component of our 2012 Notes of \$134.4 million and \$12.8 million of repayments under our Senior Credit Facility.

Our principal sources of cash from financing activities in the nine months ended September 30, 2011 were from \$230.0 million in borrowings under the 2016 Notes issued in June 2011 and proceeds from the related warrant sale of \$28.5 million. These amounts were offset by \$55.6 million in repayments under our Senior Credit Facility, \$42.9 million for the call option on our 2016 Notes, debt issuance costs of \$8.1 million, treasury stock purchases of \$69.0 million and proceeds from stock option exercises and the tax impact of stock based compensation of \$4.4 million. Working Capital

At September 30, 2012 and December 31, 2011, working capital was \$381.0 million and \$350.4 million, respectively. Amended and Restated Senior Credit Agreement

On August 10, 2010, the Company entered into an amended and restated credit agreement (the "First Amendment") with a syndicate of lending banks and further amended the agreement on June 8, 2011 (the "Second Amendment", and collectively referred to herein as the "Senior Credit Facility"). The Second Amendment increased the revolving credit component from \$450.0 million to \$600.0 million and eliminated the \$150.0 million term loan component that existed under the First Amendment, allows the Company to further increase the size of the revolving credit component by an aggregate of \$200.0 million with additional commitments, provides the Company with decreased borrowing rates and annual commitment fees, and provides more favorable financial covenants. The Second Amendment extended the Senior Credit Facility's maturity date from August 10, 2015 to September 8, 2016. Both the First Amendment and the Second Amendment are collateralized by substantially all of the assets of the Company's U.S. subsidiaries, excluding intangible assets. The Senior Credit Facility is subject to various financial and negative covenants and at September 30, 2012, the Company was in compliance with all such covenants.

On May 11, 2012, the Company entered into a first amendment to the Senior Credit Facility. The amendment modified certain financial and negative covenants as disclosed in Note 6, the effect of which was to increase the

Company's capacity to borrow.

Borrowings under the Senior Credit Facility currently bear interest, at the Company's option, at a rate equal to (i) the Eurodollar Rate (as defined in the Senior Credit Facility, which definition has not changed) in effect from time to time plus the

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applicable rate (ranging from 1.00% to 1.75%) or (ii) the highest of (x) the weighted average overnight Federal funds rate, as published by the Federal Reserve Bank of New York, plus 0.5%, (y) the prime lending rate of Bank of America, N.A. or (z) the one-month Eurodollar Rate plus 1.0%. The applicable rates are based on the Company's consolidated total leverage ratio (defined as the ratio of (a) consolidated funded indebtedness less cash in excess of \$40 million that is not subject to any restriction of the use or investment thereof to (b) consolidated EBITDA) at the time of the applicable borrowing. The Company will also pay an annual commitment fee (ranging from 0.15% to 0.3%, based on the Company's consolidated total leverage ratio) on the daily amount by which the revolving credit facility exceeds the outstanding loans and letters of credit under the credit facility.

We plan to utilize the Senior Credit Facility for working capital, capital expenditures, share repurchases, acquisitions, debt repayments and other general corporate purposes. At September 30, 2012 and December 31, 2011, there was \$321.9 million and \$179.7 million outstanding, respectively, under the Senior Credit Facility at a weighted average interest rate of 1.8% and 2.0%, respectively. The Company considers the balance to be long-term in nature based on its current intent and ability to repay the borrowing outside of the next twelve-month period. At September 30, 2012, there was approximately \$278.1 million available for borrowing under the Senior Credit Facility.

Convertible Debt and Related Hedging Activities

We pay interest each June 15 and December 15 on our \$230.0 million senior convertible notes due December 2016 ("2016 Notes") at an annual interest rate of 1.625%.

The 2016 Notes are senior, unsecured obligations of Integra, and are convertible into cash and, if applicable, shares of our common stock based on an initial conversion rate, subject to adjustment, of 17.4092 shares per \$1,000 principal amount of 2016 Notes (which represents an initial conversion price of approximately \$57.44 per share). We expect to satisfy any conversion of the 2016 Notes with cash up to the principal amount pursuant to the net share settlement mechanism set forth in the respective indenture and, with respect to any excess conversion value, with shares of our common stock. The 2016 Notes are convertible only in the following circumstances: (1) if the closing sale price of our common stock exceeds 150% of the conversion price during a period as defined in the applicable indenture; (2) if the average trading price per \$1,000 principal amount of the 2016 Notes is less than or equal to 98% of the average conversion value of the 2016 Notes during a period as defined in the applicable indenture; (3) at any time on or after September 15, 2016; or (4) if specified corporate transactions occur. The issue price of the 2012 Notes was equal to their face amounts, which is also the amount holders are entitled to receive at maturity if the 2016 Notes are not converted. None of these conditions existed with respect to the 2016 Notes; therefore the 2016 Notes are classified as long-term.

The 2016 Notes, under the terms of the applicable private placement agreement, are guaranteed fully by Integra LifeSciences Corporation, a subsidiary of Integra. The 2016 Notes are Integra's direct senior unsecured obligations and will rank equal in right of payment to all of our existing and future unsecured and unsubordinated indebtedness. In connection with the issuance of the 2016 Notes, we entered into call transactions and warrant transactions, primarily with affiliates of the initial purchasers of the 2016 Notes (the "hedge participants"). The cost of the call transactions to us was approximately \$42.9 million for the 2016 Notes. We received approximately \$28.5 million of proceeds from the warrant transactions for 2016 Notes. The call transactions involved our purchasing call options from the hedge participants, and the warrant transactions involved us selling call options to the hedge participants with a higher strike price than the purchased call options. The initial strike price of the call transactions is approximately \$57.44 for the 2016 Notes, subject to anti-dilution adjustments substantially similar to those in the 2016 Notes. The initial strike price of the warrant transactions is approximately \$70.05 for the 2016 Notes, in each case subject to customary anti-dilution adjustments.

We may from time to time seek to retire or purchase a portion of our outstanding 2016 Notes through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. Under certain circumstances, the call options associated with any repurchased 2016 Notes may terminate early, but only with respect to the number of 2016 Notes that cease to be outstanding. The amounts involved may be material.

Share Repurchase Plan

On October 29, 2010, our Board of Directors authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed \$75.0 million through December 31, 2012. Shares may be purchased either in the open market or in privately negotiated transactions. We repurchased no shares under this program during the first nine months of 2012 and \$29.1 million remains available under the authorization.

On October 23, 2012, our Board of Directors terminated the October 2010 authorization and authorized the repurchase of up to

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an additional \$75.0 million of outstanding common stock through December 2014.

## **Dividend Policy**

We have not paid any cash dividends on our common stock since our formation. Our Senior Credit Facility limits the amount of dividends that we may pay. Any future determinations to pay cash dividends on our common stock will be at the discretion of our Board of Directors and will depend upon our financial condition, results of operations, cash flows and other factors deemed relevant by the Board of Directors.

## Capital Resources

We believe that our cash and available borrowings under the Senior Credit Facility are sufficient to finance our operations and capital expenditures, and potential acquisition-related payments in the near term based on our current plans. The Company considers all such outstanding amounts to be long-term in nature based on its current intent and ability to repay the borrowings outside of the next twelve month period.

### **OTHER MATTERS**

### **Critical Accounting Estimates**

The critical accounting estimates included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 have not materially changed. We believe that of our accounting policies, the following may involve a higher degree of judgment, estimates and complexity.

Valuation of Goodwill, Identifiable Intangible Assets, In-Process Research and Development Charges We review goodwill, identifiable intangible assets with indefinite lives and capitalized in-process research and development for impairment annually. We continually assess whether events or changes in circumstances represent a 'triggering' event that would require us to complete an impairment assessment. Factors that we consider in determining whether a triggering event has occurred include a significant change in the business climate, legal factors, operating performance indicators, competition, sale or disposition of significant assets or products, or the termination of development programs. Application of these impairment tests requires significant judgments, including estimation of future cash flows, which is dependent on internal forecasts, estimation of the long-term rate of growth for our business, the useful life over which cash flows will occur and determination of our weighted-average cost of capital. Should a triggering event be deemed to occur, and for each of the annual goodwill impairment assessments, we are required to estimate the expected net cash flows to be realized over the life of the asset and/or the asset's fair value. Fair values are determined by a discounted cash flow model. These estimates are also subject to significant management judgment including the determination of many factors such as revenue growth rates, cost growth rates, terminal value assumptions and discount rates. Changes in these estimates can have a significant impact on the determination of cash flows and fair value and could potentially result in future material impairments. At January 1, 2012, we adopted the Financial Accounting Standard Update No. 2011-08, Intangibles - Goodwill and Other that may allow us to skip the annual two-step test by performing the optional qualitative assessment for testing goodwill for impairment (qualitative screen). The qualitative screen permits us to qualitatively assess whether it is more likely than not (i.e., a likelihood of greater than 50%) that the fair value of a reporting unit is less than its carrying amount. If that is the case, we would have to perform the annual two-step test. If we conclude otherwise, we have completed our goodwill impairment test and do not need to perform the two-step test.

We test our goodwill for impairment at least annually on July 31 of each year. Historically, goodwill was tested annually for impairment as of June 30 of each fiscal year. Effective in the quarter ended June 30, 2012, we adopted a new accounting principle whereby the annual impairment review of goodwill will be performed as of July 31 of each year. We performed an assessment of the goodwill in each of our reporting units during the first quarter of 2012 and on July 31, 2012. On July 31, 2012, the Company performed the annual goodwill impairment test. The Company first assessed the qualitative factors to determine whether it is more likely than not that the fair value of the reporting units is less than their carrying amounts. The Company performed this qualitative assessment for seven reporting units that each had an estimated fair value that was in excess of its carrying value by a significant amount. For each of these reporting units, the Company weighed the relative impact of factors that are specific to the reporting unit as well as industry and macroeconomic factors. The reporting unit specific factors that were considered included the results of the most recent impairment tests, as well as financial performance and changes to the reporting units' carrying

amounts since the most recent impairment tests. The Company concluded that each of the reporting unit specific and industry factors had either a positive or neutral impact on their fair values. The Company also determined that macroeconomic factors during 2012 did not have a significant impact on the discount rates and growth rates

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used for the January 1 tests. Based on the qualitative assessment, the Company concluded that for these seven reporting units, it is more likely than not that their carrying values are less than their fair values at July 31, 2012.

The Company performed the first step of the goodwill impairment test for its U.S. Spine business. This component has \$31.7 million of allocated goodwill. As a result of the annual impairment assessment, the Company determined that the fair value exceeded its carrying value by approximately 13% at July 31, 2012. However, if future results do not meet or exceed the Company's forecasts, or if unfavorable changes occur in the weighted-average cost of capital, growth assumptions for future revenue, terminal value growth rate and/or forecasted cash flows utilized in the discounted cash flow analysis, the Company may record an impairment of this goodwill at a future date. Our assessment of whether any triggering events occurred through the quarter ended September 30, 2012 for which we should further analyze whether an impairment exists through that date did not result in the identification of such triggering events.

Recently Issued and Adopted Accounting Standards

On July 27, 2012, the Financial Accounting Standard Board issued Accounting Standards Update No. 2012-02, Testing Indefinite-Lived Intangible Assets for Impairment. The revised standard is intended to reduce the cost and complexity of testing indefinite-lived intangible assets other than goodwill for impairment by providing entities with an option to perform a "qualitative" assessment to determine whether further impairment testing is necessary. The revised standard allows an entity first to assess qualitative factors to determine whether events and circumstances indicate that it is more likely than not (that is, a likelihood of more than 50 percent) that an indefinite-lived intangible asset is impaired. If it is more likely than not that the asset is impaired, the entity must calculate the fair value of the asset, compare the fair value to its carrying amount, and record an impairment charge, if the carrying amount exceeds fair value. However, if an entity concludes that it is not more likely than not that the asset is impaired, no further action is required. The qualitative assessment is not an accounting policy election. An entity can choose to perform the qualitative assessment on none, some, or all of its indefinite-lived intangible assets. Moreover, an entity can bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to the quantitative impairment test, and then choose to perform the qualitative assessment in any subsequent period. The revised standard is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. However, an entity can choose to early adopt the revised standard even if its annual or interim impairment test date is before July 27, 2012 (the date on which the revised standard was issued), provided that its financial statements for the most recent annual or interim period have not yet been issued. The Company elected to adopt this standard early and such adoption did not have a material impact on the Company's financial statements.

### ITEM 3. OUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, including changes in foreign currency exchange rates and interest rates that could adversely affect our results of operations and financial condition. To manage the volatility relating to these typical business exposures, we may enter into various derivative transactions when appropriate. We do not hold or issue derivative instruments for trading or other speculative purposes.

Foreign Currency Exchange and Other Rate Risks

We operate on a global basis and are exposed to the risk that changes in foreign currency exchange rates could adversely affect our financial condition, results of operations and cash flows. We are primarily exposed to foreign currency exchange rate risk with respect to transactions and net assets denominated in euros, Swiss francs, British pounds, Canadian dollars, and Australian dollars. We manage the foreign currency exposure centrally, on a combined basis, which allows us to net exposures and to take advantage of any natural offsets. To mitigate the impact of currency fluctuations on transactions denominated in nonfunctional currencies, we periodically enter into derivative financial instruments in the form of foreign currency exchange forward contracts with major financial institutions. We temporarily record realized and unrealized gains and losses on these contracts that qualify as cash flow hedges in other comprehensive income, and then recognize them in other income or expense when the hedged item affects net earnings.

From time to time, we enter into foreign currency forward exchange contracts with terms of up to 12 months to manage currency exposures for transactions denominated in a currency other than an entity's functional currency. As a result, the impact of foreign currency gains/losses recognized in earnings are partially offset by gains/losses on the related foreign currency forward exchange contracts in the same reporting period.

We maintain written policies and procedures governing our risk management activities. With respect to cash flow hedges, changes in cash flows attributable to hedged transactions are generally expected to be completely offset by changes in the fair value of hedge instruments. Consequently, foreign currency exchange contracts would not subject us to material risk due to

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exchange rate movements, because gains and losses on these contracts offset gains and losses on the assets, liabilities or transactions being hedged.

The results of operations discussed herein have not been materially affected by inflation.

Interest Rate Risk

Cash and Cash Equivalents - We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash and cash equivalents. A hypothetical 100 basis point movement in interest rates applicable to our cash and cash equivalents outstanding at September 30, 2012 would increase interest income by approximately \$1.3 million on an annual basis. No significant decrease in interest income would be expected as our cash balances are earning interest at rates close to zero. We are subject to foreign currency exchange risk with respect to cash balances maintained in foreign currencies.

Senior Credit Facility - Our interest rate risk relates primarily to U.S. dollar LIBOR-indexed borrowings. We have used an interest rate derivative instrument to manage our earnings and cash flow exposure to changes in interest rates by utilizing a forward-starting interest rate swap that began to offset a portion of our interest payments in the first quarter of 2011. This interest rate derivative instrument fixed the interest rate on a portion of our expected LIBOR-indexed floating-rate borrowings beginning on December 31, 2010. The interest rate swap had a notional amount of \$131.3 million outstanding as of September 30, 2012. We recognized \$1.4 million of additional interest expense related to this derivative during the nine month of 2012. The fair value of our interest rate derivative instrument was a net liability of \$4.6 million at September 30, 2012.

Based on our outstanding borrowings at September 30, 2012, a one-percentage point change in interest rates would have impacted interest expense on the unhedged portion of the debt by \$1.9 million on an annualized basis.

### ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Management has designed our disclosure controls and procedures to provide reasonable assurance of achieving the desired control objectives.

As required by Exchange Act Rule 13a-15(b), we have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2012. Based upon this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2012 to provide such reasonable assurance.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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### PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

We are subject to various claims, lawsuits and proceedings in the ordinary course of our business, including claims by current or former employees, distributors and competitors and with respect to our products. In the opinion of management, such claims are either adequately covered by insurance or otherwise indemnified, or are not expected, individually or in the aggregate, to result in a material adverse effect on our financial condition. However, it is possible that our results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies.

On June 6, 2012, the Company was contacted by the United States Attorney's Office for the District of New Jersey regarding the activities of two sales representatives in a single region within our Extremities Reconstruction division pertaining to the alleged creation of invoices for products that were not sold or surgeries that did not take place for extremities indications. The Company is cooperating with the United States Attorney's office on a voluntary basis and is not a subject or target of an investigation at this time.

### ITEM 1A. RISK FACTORS

The Risk Factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 (as modified by the subsequent Quarterly Report on Form 10-Q for the period ended June 30, 2012) have not materially changed other than the modifications to the risk factors as set forth below.

To market our products under development we will first need to obtain regulatory approval. Further, if we fail to comply with the extensive governmental regulations that affect our business, we could be subject to penalties and could be precluded from marketing our products.

As a manufacturer and marketer of medical devices, we are subject to extensive regulation by the FDA and the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling, promotion and sales of the devices, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the import and export of devices and other matters. We are facing an increasing amount of scrutiny and compliance costs as more states are implementing regulations governing medical devices, pharmaceuticals and/or biologics which affect many of our products. As a result, we have been implementing additional procedures, controls and tracking and reporting processes, as well as paying additional permit and license fees, where required.

Our products under development are subject to FDA approval or clearance prior to marketing for commercial use. The process of obtaining necessary FDA approvals or clearances can take years and is expensive and uncertain. The FDA has implemented changes to the 510(k) premarket notification process. The FDA has issued a new Draft Guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k)." These changes to the 510(k) process may result in more extensive testing, clinical trial data, more extensive manufacturing information and postmarket surveillance requirements.

Our inability to obtain required regulatory approval on a timely or acceptable basis could harm our business. Further, approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed, warnings that may be required to accompany the product or additional restrictions placed on the sale and/or use of the product. Further studies, including clinical trials and FDA approvals, may be required to gain approval for the use of a product for clinical indications other than those for which the product was initially approved or cleared or for significant changes to the product. These studies could take years to complete and could be expensive, and there is no guarantee that the results will convince the FDA to approve or clear the additional indication. Any negative outcome in our clinical trials, including as a result of any interim analysis which we may do with respect to our clinical trials from time to time, could adversely affect our ability to launch new products, which could affect our sales and our ability to achieve reimbursement for new or existing products. In addition, for products with an approved PMA, the FDA requires annual reports and may require post-approval surveillance programs and/or

studies to monitor the products' safety and effectiveness. Results of post-approval programs may limit or expand the further marketing of the product. We are also seeing third-party payors require clinical trial data for products cleared through the 510(k) process in order to continue reimbursement coverage. There is also no guarantee that the payors will agree to continue reimbursement or provide additional coverage based upon these clinical trials. These clinical trials could take years to complete and be expensive, and there is no guarantee that the FDA will approve the additional indications for use. If the FDA does not approve the additional indications for use, our ability to obtain reimbursement for these products and our ability to compete against alternative products or technologies could suffer and, consequently, affect our sales.

Another risk of application to the FDA relates to the regulatory classification of new products or proposed new uses for existing

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products. In the filing of each application, we make a judgment about the appropriate form and content of the application. If the FDA disagrees with our judgment in any particular case and, for example, requires us to file a Premarket Approval (PMA) application rather than allowing us to market for approved uses while we seek broader approvals or requires extensive additional clinical data, the time and expense required to obtain the required approval might be significantly increased or approval might not be granted. Furthermore, the timing of approvals in the U.S. and Europe is now dependent on the class of product. Any of our Class III devices (those categorized as supporting or sustaining human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury) and products of animal origin take an extensive amount of time to obtain approval in the European Union and all require clinical reports or clinical trial data which can be costly. The FDA Safety and Innovation Act (FDASIA) which includes the Medical Device User Fee Amendments of 2012 (MDUFA III), as well as other medical device provisions, went into effect October 1, 2012. This includes performance goals and user fees paid to FDA by medical device companies when they register and list with FDA and when they submit an application to market a device in the US. This will affect the fees paid to the FDA over the 5 year period that FDASIA is in effect.

Our manufacturing facilities must be in compliance with FDA Quality System Regulations (current Good Manufacturing Practices). In addition, approved products are subject to continuing FDA requirements relating to quality control and quality assurance, maintenance of records, reporting of adverse events and product recalls, documentation, and labeling and promotion of medical devices. For example, some of our orthobiologics products are subject to FDA and certain state regulations regarding human cells, tissues, and cellular or tissue-based products, which include requirements for Establishment Registration and listing, donor eligibility, current good tissue practices, labeling, adverse-event reporting, and inspection and enforcement. Some states have their own tissue banking regulation. We are licensed or have permits as a tissue bank in California, Florida, New York and Maryland. In addition, tissue banks may undergo voluntary accreditation by the AATB. The AATB has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become a licensed tissue bank. The FDA and foreign regulatory authorities require that our products be manufactured according to rigorous standards. These and future regulatory requirements could significantly increase our production or purchasing costs and could even prevent us from making or obtaining our products in amounts sufficient to meet market demand. If we or a third-party manufacturer change our approved manufacturing process, the FDA may require a new approval before that process may be used. Failure to develop our manufacturing capability could mean that, even if we were to develop promising new products, we might not be able to produce them profitably, as a result of delays and additional capital investment costs.

All of our manufacturing facilities, both international and domestic, are also subject to inspections by or under the authority of the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements could subject us to issuance of FDA Form 483 Inspectional Observations, warning letters or enforcement action by the FDA or other agencies, including product seizures, recalls, withdrawal of clearances or approvals, restrictions on or injunctions against marketing our product or products based on our technology, denials of requests for exportation certificates to foreign governments, cessation of operations and civil and criminal penalties, any of which could materially affect our business.

The FDA inspected our Plainsboro, New Jersey regenerative medicine manufacturing facility during the third quarter of 2011, at the conclusion of which it issued FDA Form 483 inspectional observations that described violations of quality system regulations. We subsequently received a warning letter from the FDA dated December 21, 2011 pertaining to that facility. We filed the warning letter as an exhibit to a Current Report on Form 8-K filed January 5, 2012. The effect of the warning letter is to require regular reports to the FDA of progress made on remediation of issues identified in the warning letter. Further, the FDA will not approve new Premarket Approval Applications (PMA) for products manufactured in that facility until the warning letter has been remediated.

In June and July 2012, the FDA again inspected the regenerative medicine facility. The FDA was on site for 20 days of inspection, during which the agency both specifically reviewed the progress of the facility's warning letter remediation program and comprehensively reviewed its quality systems. At the end of the inspection, the FDA issued a new FDA Form 483 with seven observations, relating to Corrective and Preventative Action ("CAPA"),

non-conforming products, production and process controls, certain software validations, certain document control procedures, control of storage areas and stock rooms and delays in the filing of supplemental Medical Device Reports. Of these, the FDA designated the first observation, related to CAPA, as a repeat observation. The FDA did not issue repeat observations about the suitability of the building for manufacturing, preventative maintenance, cleaning validations, root-cause analysis of non-conforming products or filing initial Medical Device Reports within the required 30 days.

We have incurred, and will incur, expenses to remediate those observations and others issued in connection with other inspections at other facilities, and to prepare our manufacturing facilities for anticipated FDA inspections. The FDA has

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notified us that it will not grant requests for exportation certificates to foreign governments until the violations identified in the warning letter have been corrected. If such remediation cannot be completed in a timely manner we may not be able to produce certain products for a period of time or may not be able to sell such products in certain markets. There can be no assurance that such remediation and preparation activities will address all such observations to the FDA's satisfaction, or that the FDA will not impose additional regulatory sanctions with respect to such observations. We manufacture medical devices that are subject to various electrical safety standards. Many countries have adopted the recommendations of the International Electrotechnical Commission ("IEC") for the safety and effectiveness of medical electrical equipment. The IEC is a non-profit, non-governmental international standards organization that prepares and publishes International Standards for all electrical, electronic and related technologies. Their updated standards are being implemented in some markets starting in July 2012 and will continue to be adopted over the following years worldwide. If we cannot comply with these standards, we may not be able to sell some of our products in the affected markets. Most of our affected products have already been modified to meet the new standards and are substantially in compliance with these standards. Except in limited circumstances, we do not anticipate any delays in selling our products in the markets that have adopted the IEC updated standards.

We are also subject to other regulatory requirements of countries outside the United States where we do business. For example, under the European Union Medical Device Directive (MDD), all medical devices must meet the Medical Device Directive standards in order to obtain CE Mark Certification prior to marketing in the EU. CE Mark Certification requires a comprehensive Quality System program, comprehensive technical and clinical documentation and data on the product, which a Notified Body in the EU reviews. In addition, we must be certified to the ISO 13485:2003 Quality System standards and maintain this certification in order to market our products in the EU, Canada, Japan, Latin America, countries in the Asia-Pacific region and most other countries outside the United States. The EU has revised the Medical Device Directive (93/42/EC as amended by 2007/47/EC). Compliance with these regulations requires extensive documentation, clinical reports for all products sold in the EU and other requirements. Requirements to meet these regulations can be costly and are mandatory to market our products in the EU. Many other countries have instituted new medical device regulations and/or revised current medical device regulations. These regulations often require extensive documentation, including clinical data and may require audits of our manufacturing facilities in order to gain approval to sell our products in that country. There are also associated fees with these new regulations. These regulations are required for all new products and re-registration of our medical devices, and may involve lengthy and expensive reviews.

Our products that contain human derived tissue, including those containing demineralized bone matrices, are not medical devices in the EU as defined in the Medical Device Directive (93/42/EC). They are also not medicinal products as defined in Directive 2001/83/EC. Today, regulations, if applicable, differ from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the EU, as well as for other countries, the approval process for human-derived cell or tissue based medical products may be extensive, lengthy, expensive, and unpredictable. Among others, some of our orthobiologics products are subject to EU member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. These EU member states' regulations include requirements for registration, listing, labeling, adverse-event reporting, and inspection and enforcement. Some EU member states have their own tissue banking regulations. In addition, certain EU member states have instituted new requirements for additional testing that may be prohibitive to obtaining approval in those member states.

Oversight of the medical device industry might affect the manner in which we may sell medical devices and compete in the marketplace.

There are laws and regulations that govern the means by which companies in the healthcare industry may market their products to healthcare professionals and may compete by discounting the prices of their products, including for example, the federal Anti-Kickback Statute, the federal False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996, state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, in some instances civil and criminal penalties, damages, fines, exclusion from

participation in federal and state healthcare programs, including Medicare and Medicaid. Although we exercise care in structuring our sales and marketing practices and customer discount arrangements to comply with those laws and regulations, we cannot assure you that:

government officials charged with responsibility for enforcing those laws will not assert that our sales and marketing practices or customer discount arrangements are in violation of those laws or regulations; or government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. Correspondingly, federal and state laws are also sometimes open to interpretation, and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

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AdvaMed, the principal United States trade association for the medical device industry, promulgates a model code of conduct that sets forth standards by which its members should abide in the promotion of their products. We have in place policies and procedures for compliance that we believe are at least as stringent as those set forth in the revised AdvaMed Code, and we provide routine training to our sales and marketing personnel on our policies regarding sales and marketing practices. Pursuant to the revised AdvaMed Code, we have certified our adoption of the revised AdvaMed Code. Nevertheless, the sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. For example, recent federal legislation, state legislation and foreign legislation would require detailed disclosure of gifts and other remuneration made to health care professionals. In addition, prosecutorial scrutiny and governmental oversight, on the state and federal levels, over some major device companies regarding the retention of healthcare professionals as consultants has limited the manner in which medical device companies may retain healthcare professionals as consultants. Various hospital organizations, medical societies and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies or ban or restrict certain marketing and sales practices such as gifts and business meals.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In October 2010, our Board of Directors adopted a program that authorizes us to repurchase shares of our common stock for an aggregate purchase price not to exceed \$75.0 million through December 31, 2012. Shares may be repurchased either in the open market or in privately negotiated transactions.

There were no purchases of our common stock during the nine months ended September 30, 2012 under this program. ITEM 4. MINE SAFETY DISCLOSURES Not applicable.

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Item 6.

### **EXHIBITS**

*31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
*32.2	Certification of Principal Financial Officer 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.DEF	XBRL Definition Linkbase Document
*†101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
*†101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith

The financial information of Integra LifeSciences Holdings Corporation Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 filed on October 24, 2012 formatted in XBRL (Extensible Business

Reporting Language): (i) the Condensed Consolidated Statements of Operations and Comprehensive Income, (ii) the Condensed Consolidated Balance Sheets, (iii) Parenthetical Data to the Condensed Consolidated Balance Sheets, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, is furnished electronically herewith.

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### **SIGNATURES**

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

INTEGRA LIFESCIENCES HOLDINGS

**CORPORATION** 

Date: October 24, 2012 /s/ Peter J. Arduini

Peter J. Arduini

President and Chief Executive Officer

Date: October 24, 2012 /s/ John B. Henneman, III

John B. Henneman, III

Executive Vice President, Finance and

Administration,

and Chief Financial Officer

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† (ii) the Condensed Consolidated Balance Sheets, (iii) Parenthetical Data to the Condensed Consolidated Balance Sheets, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, is furnished electronically herewith.