

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 March 31, 2005

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 No

Indicate by check mark whether the registrant is an accelerated filer (as
defined in Rule 12b-2 of the Act). Yes No

The number of shares of the registrant's Common Stock, \$.01 par value,
outstanding as of May 5, 2005 was 29,391,459.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
 CONSOLIDATED STATEMENTS OF OPERATIONS
 (UNAUDITED)

(In thousands, except per share amounts)

Three Months Ended March 31, 2005 2004 ---- ----

TOTAL REVENUE			
			\$
65,839	\$ 52,443	COSTS AND EXPENSES	Cost of product
revenues		24,133	
	20,001	Research and development	
		3,359	2,823
	23,916	Selling, general and administrative	
of intangible assets	17,007	Amortization	
883		1,475	
		Total costs and expenses	
		52,883	40,714
	Operating income		
		12,956	
	11,729	Interest income	
		954	928
	Interest expense		
		(927)	
	(871)	Other expense, net	
		(93)	(17)
	Income before income taxes		
		12,890	11,769
	Income tax expense		
		4,447	4,331
	Net income		
			\$
8,443	\$ 7,438	Basic net income	
per share		\$ 0.28	\$
	0.25	Diluted net income per share	
		\$ 0.26	\$ 0.23
	Weighted average common shares outstanding	Basic	
		30,561	29,704
	Diluted		
		35,144	34,373

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

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

(In thousands, except per share amounts)

	March 31, 2005	December 31, 2004
ASSETS		
Current Assets: Cash and cash equivalents	\$ 32,763	\$ 69,855
Short-term investments	43,705	43,705
Accounts receivable, net of allowances of \$3,326 and \$2,749	51,261	51,261
Inventories	46,765	65,335
Prepaid expenses and other current assets	11,894	12,716
Total current assets	204,958	216,238
Non-current investments	81,463	95,172
Property, plant, and equipment, net	27,685	25,461
Deferred income taxes, net	9,255	15,787
Identifiable intangible assets, net	70,547	59,817
Goodwill	71,789	39,237
Other assets	4,710	5,001
Total assets	\$ 470,407	\$ 456,713
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities: Accounts payable, trade	14,543	10,160
Income taxes payable	1,922	1,022
Accrued expenses and other current liabilities	14,514	13,052
Total current liabilities	30,979	24,234
Long term debt	118,631	118,900
Deferred revenue	287	310
Other liabilities	6,165	5,446
Total liabilities	156,062	148,890
Stockholders' Equity: Common stock; \$0.01 par value; 60,000 authorized shares; 29,344 and 29,202 issued at March 31, 2005 and December 31, 2004, respectively	293	292
Additional paid in capital	323,391	320,602
Treasury stock, at cost; 718 shares at March 31, 2005 and December 31, 2004	(19,474)	(19,474)
Accumulated other comprehensive income (loss): Unrealized gain on available for sale securities	(1,273)	(818)
Foreign currency translation adjustment	4,966	9,266
Minimum pension liability adjustment	(1,736)	(1,780)
Retained earnings/(Accumulated deficit)	8,178	(265)
Total stockholders' equity	314,345	307,823
Total liabilities and stockholders' equity	\$ 470,407	\$ 456,713

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

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

(In thousands) Three Months Ended March 31, 2005 2004

~~----- OPERATING ACTIVITIES: Net income~~

\$ 8,443	\$ 7,438	Adjustments to reconcile net income to net cash provided by operating activities:
		Depreciation and amortization
		2,722 2,162
		Deferred income tax provision
		3,106 3,159
		Amortization of discount and premium on investments
		541 587 Other, net
<hr/>		
		174 (13) Changes in assets and liabilities, net of business acquisitions: Accounts receivable
		(746)
		(1,129) Inventories
<hr/>		
		(6,011) (3,327) Prepaid expenses and other current assets
		686 481 Non-current assets
		221 20 Accounts payable, accrued expenses and other liabilities
		4,097 1,472 Net cash provided by operating activities
		13,233 10,850
<hr/>		
----- INVESTING ACTIVITIES: Proceeds from		
		sales/maturities of available for sale investments
		4,150 71,918 Purchases of available for sale investments
		(4,350) (82,334)
		Cash used in business acquisition, net of cash acquired
		(49,348) (3,890) Purchases of property and equipment
		(2,781) (2,875) Net cash used in investing activities
		(52,329) (17,181)
<hr/>		
----- FINANCING		
		ACTIVITIES: Proceeds from exercised stock options and warrants
		2,285 1,236 Repayment of bank loans
		(5)
		Net cash provided by financing activities
		2,280 1,236
		Effect of exchange rate changes on cash
		(276) 68 Net decrease in cash and cash equivalents
		(37,092) (5,027) Cash and cash equivalents at beginning of period
		69,855 26,054
		Cash and cash equivalents at end of period
		\$ 32,763 \$ 21,027

~~=====~~

Supplemental cash flow information:

At March 31, 2005 and 2004, the Company had \$3.3 million and \$2.2 million, respectively, of cash pledged as collateral in connection with its interest rate swap agreement.

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

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

BASIS OF PRESENTATION

General

In the opinion of management, the March 31, 2005 unaudited consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation 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 consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2004 included in the Company's Annual Report on Form 10-K. Operating results for the three-month period ended March 31, 2005 are not necessarily indicative of the results to be expected for the entire year.

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States 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, net realizable value of inventories, estimates of future cash flows associated with long-lived asset valuations, depreciation and amortization periods for long-lived assets, valuation allowances recorded against deferred tax assets, 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.

In 2004, the Company determined that its investments in auction rate securities should be classified as short term investments. Auction rate securities are reset to current interest rates periodically, but no later than every 90 days. These securities were previously recorded in cash and cash equivalents due to the liquidity provided by their short-term pricing reset features and the Company's ability to liquidate them in monthly auctions. Prior period cash flow information has been revised to conform to the current year presentation. Accordingly, cash flows from investing activities decreased by \$2.1 million in the three months ended March 31, 2004. There was no impact on the Company's net income or cash flows from operations or financing activities as a result of this revision. The Company does not have any debt covenants that are affected by reported cash balances.

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

Recently Issued Accounting Standards and Other Matters

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 151, "Inventory Costs-an amendment of ARB No. 43, Chapter 4" (Statement 151), which is effective beginning January 1, 2006. Statement 151 requires that abnormal amounts of idle facility expense, freight, handling costs and wasted material be recognized as current period charges. Statement 151 also requires that the allocation of fixed production overhead be based on the normal capacity of the production facilities. We are currently assessing the potential effect that Statement 151 could have on our financial position or results of operations.

In March 2004, the FASB Emerging Issue Task Force (EITF) reached a consensus on Issue 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments". Issue 03-01 provides guidance regarding recognition and measurement of unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, "Accounting for Certain Investments in Debt and Equity Securities". The application of certain paragraphs covering the measurement provisions of Issue 03-01 have been deferred pending the issuance of a final FASB Staff Position providing implementation guidance on Issue 03-01. The disclosures were effective in annual financial statements for fiscal years ending after December 15, 2003.

Management is currently assessing the impact that the recognition and measurement provisions of Issue 03-01 could have on our financial statements.

The American Jobs Creation Act of 2004 (the "Act") was signed into law in October 2004 and has several provisions that may impact the Company's income taxes in the future, including the repeal of the extraterritorial income exclusion and a deduction related to qualified production activities taxable income. The FASB proposed that the qualified production activities deduction is a special deduction and will have no impact on deferred taxes existing at the enactment date. Rather, the impact of this deduction will be reported in the period in which the deduction is claimed on the Company's tax return. Management is currently evaluating the impact of the FASB guidance related to qualified production activities on the Company's effective tax rate in future periods.

In December 2004, the FASB issued Statement No. 123 (revised 2004), "Share-Based Payment," which is a revision of Statement No. 123, "Accounting for Stock-Based Compensation." Statement 123(R) replaces APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends Statement No. 95, "Statement of Cash Flows." Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value. Pro forma footnote disclosure will no longer be an alternative to financial statement recognition.

Statement 123(R) must be adopted no later than January 1, 2006. Statement 123(R) permits companies to adopt its requirements using either the "modified prospective" method or the "modified retrospective" method. Management is currently evaluating the potential impact of Statement 123(R) on our consolidated financial position and results of operations and the alternative adoption methods.

Equity-Based Compensation

The Company recognizes employee stock based compensation using the intrinsic value method prescribed by APB Opinion No. 25 "Accounting for Stock Issued to Employees" and FASB Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation - an interpretation of APB Opinion No. 25".

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Had the compensation cost for the Company's stock option plans been determined based on the fair value at the date of grant consistent with the provisions of SFAS No. 123, the Company's net income and basic and diluted net income per share would have been as follows:

Three Months Ended March 31, 2005		2004	
----- (in thousands, except per share amounts)			
		Net income: As reported	

	\$ 8,443	\$ 7,438	Less: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects
	(1,729)	(1,470)	----- Pro forma
	\$ 6,714	\$ 5,968	Net income per share: Basic: As reported
	\$ 0.28	\$ 0.25	----- Pro forma
	\$ 0.22	\$ 0.20	Diluted: As reported
	\$ 0.26	\$ 0.23	----- Pro forma
	\$ 0.21	\$ 0.19	-----

As options vest over a varying number of years and awards are generally made each year, the pro forma impacts shown above may not be representative of future pro forma expense amounts. The pro forma additional compensation expense related to all options granted prior to October 1, 2004 was calculated based on the fair value of each option grant using the Black-Scholes model, while the pro forma additional compensation expense related to all options granted on or after October 1, 2004 was calculated based on the fair value of each option grant using the binomial distribution model.

BUSINESS ACQUISITIONS

On January 3, 2005, the Company acquired all of the outstanding capital stock of Newdeal Technologies SA for 38.3 million euros (\$51.9 million) in cash, subject to a working capital adjustment. Additionally, the Company has agreed to pay the sellers up to an additional 1,250,000 euros if each of the sellers continues his employment with Integra through January 3, 2006. This additional 1,250,000 euro payment is being accrued to general and administrative expense on a straight-line basis over the one year employment requirement period.

Based in Lyon, France, Newdeal is a leading developer and marketer of specialty implants and instruments specifically designed for foot and ankle surgery. Newdeal's products include a wide range of products for the forefoot, the mid-foot and the hind foot, including the Bold(R) Screw, Hallu-Fix(R) plate system and the HINTEGRA(R) total ankle prosthesis. The company sells its products through a direct sales force in France, Belgium and the Netherlands, and through distributors in more than 30 countries, including the United States and Canada. Newdeal's target physicians include orthopedic surgeons specializing in injuries of the foot, ankle and extremities, as well as podiatric surgeons. The goodwill recorded in connection with this acquisition is based on the benefits the Company expects to generate from the synergy between Newdeal's reconstructive foot and ankle fixation products and Integra's regenerative products that are used in the treatment of chronic and traumatic wounds of the foot and ankle.

The following summarizes the preliminary fair value of the assets acquired and liabilities assumed:

(All amounts in thousands)		
Cash	\$ 2,520	
Other current assets	8,477	
Property, plant and equipment	1,120	Wtd. Avg. Life
Intangible assets:		
— Tradename	2,926	37 years
— Customer relationships	6,032	10 years
— Technology	3,387	10 years
— Non-competition agreement	745	5 years
Goodwill	34,786	
Other assets	43	
<hr/>		
— Total assets acquired	60,036	
<hr/>		
Liabilities assumed, excluding debt ..	7,640	
Debt assumed	529	
<hr/>		
Net assets acquired	\$51,867	

~~The preliminary fair value of assets acquired and liabilities assumed was determined with the assistance of a third party valuation firm. The Company is in the process of finalizing its estimates of fair value for certain tangible assets acquired in this acquisition and expects to complete this process by the end of the second quarter.~~

~~The acquired intangible assets are being amortized over lives ranging from 5 to 40 years.~~

~~In May 2004, the Company acquired the MAYFIELD(R) Cranial Stabilization and Positioning Systems and the BUDDE(R) Halo Retractor System business from Schaefer Mayfield USA, Inc. (formerly Ohio Medical Instrument Company) for \$20.0 million in cash paid at closing, a \$0.3 million working capital adjustment, and \$0.3 million of acquisition related expenses. The MAYFIELD and BUDDE lines include skull clamps, headrests, reusable and disposable skull pins, blades, retractor systems, and spinal implants. MAYFIELD systems are the market leader in the United States and have been used by neurosurgeons for over thirty years. The products are sold in the United States through the Integra NeuroSciences direct sales organization and in international markets through distributors.~~

~~In May 2004, the Company acquired all of the capital stock of Berchtold Medizin Elektronik GmbH, now named Integra ME, from Berchtold Holding GmbH for \$5.0 million in cash. Integra ME manufactures and markets the ELEKTROTOM(R) line of electrosurgery generators and the SONOTOM(R) ultrasonic surgical aspirator, as well as a broad line of related handpieces, instruments and disposables used in many surgical procedures, including neurosurgery. Integra ME markets and sells its products to hospitals and physicians primarily through a network of distributors.~~

~~In January 2004, the Company acquired the R&B instrument business from R&B Surgical Solutions, LLC for \$2.0 million in cash. The R&B instrument line is a complete line of high quality handheld surgical instruments used in neuro and spinal surgery. The Company markets these products through its JARIT sales organization.~~

~~In January 2004, the Company acquired the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. for \$1.6 million in cash. The Sparta product line includes products used in plastic and reconstructive, ear, nose and throat (ENT), neuro, ophthalmic and general surgery. The Company sells the Sparta products through a direct marketing organization and an existing distributor network.~~

The goodwill acquired in the MAYFIELD/BUDDE, R&B, and Sparta acquisitions is expected to be deductible for tax purposes.

The following unaudited pro forma financial information summarizes the results of operations for the three months ended March 31, 2004 as if the acquisitions consummated in 2005 and 2004 had been completed as of the beginning of that period. 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 increased depreciation expense, increased intangible asset amortization, and increased income taxes at a rate consistent with Integra's effective rate in each year. No effect has been given to cost reductions or operating synergies. As a result, these pro forma results do not necessarily represent results that would have occurred if the acquisition had taken place on the basis assumed above, nor are they indicative of the results of future combined operations.

Three Months Ended March 31, 2004
(in thousands) Total revenue

.....
\$61,494 Net income

.....
8,018 Basic net income per share

..... \$ 0.27 Diluted
net income per share

..... \$ 0.25

Because the Newdeal acquisition was consummated on January 3, 2005, the Company's results of operations for the three months ended March 31, 2005 would not have been materially different from those presented herein.

INVENTORIES

Inventories consisted of the following:

March 31, December 31, 2005 2004
(in thousands) Raw

materials.....

\$13,131 \$11,961 Work in

process.....

9,189 7,496 Finished

goods.....

43,015 36,490 \$65,335

\$55,947 =====

GOODWILL AND OTHER INTANGIBLE ASSETS

Changes in the carrying amount of goodwill for the three months ended March 31, 2005, were as follows:

Balance at December 31, 2004 \$ 30,237

Newdeal acquisition 34,786

Foreign currency translation (2,234)

Balance at March 31, 2005 \$ 71,789

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

March 31, 2005
 December 31, 2004
 Weighted

— Average
 Accumulated
 Accumulated Life
 Cost Amortization
 Cost Amortization

(in thousands)
 Completed
 technology
 14 years
 \$ 20,089 \$
 (4,833) \$ 17,108
 \$ (4,505)
 Customer
 relationships
 17 years
 23,116 (3,632)
 17,417 (3,214)
 Trademarks/brand
 names 36
 years 31,449
 (2,120) 28,689
 (1,862)
 Noncompetition
 agreements... 5
 years 7,039
 (1,551) 6,352
 (1,198) All other

 11 years 2,233
 (1,243) 2,233
 (1,203)

\$ 83,926
 \$(13,379) \$
 71,799 \$(11,982)
 Accumulated
 amortization ..
 (13,379) (11,982)
 \$ 70,547 \$ 59,817
 =====

Annual amortization expense is expected to approximate \$5.9 million in 2005, \$5.8 million in 2006, \$5.5 million in 2007, \$5.2 million in 2008, and \$4.5 million in 2009. Identifiable intangible assets are initially recorded at fair market value at the time of acquisition generally using an income or cost approach.

5. RETIREMENT BENEFIT PLANS

The Company maintains defined benefit pension plans that cover employees in its manufacturing plants located in Andover, United Kingdom and Tuttlingen, Germany. Net periodic benefit costs for the Company's defined benefit pension plans included the following amounts:

Three Months Ended March 31 2005
 2004 (in
 thousands) Service cost

 \$ 61 \$ 31 Interest cost

 103 92 Expected return on plan
 assets (86) (79)
 Recognized net actuarial loss
 35 37

~~Net periodic benefit cost~~

~~..... \$ 113 \$ 81~~

~~For the three months ended March 31, 2005, the Company made \$41,000 of contributions to its defined benefit pension plans.~~

~~6. COMPREHENSIVE INCOME~~

~~Comprehensive income was as follows:~~

Three Months Ended March 31,	2005	2004
(in thousands) Net income		
\$ 8,443	\$ 7,438	Foreign currency translation adjustment
(4,256)	(205)	Unrealized holding gains (losses) on available for sale securities, net of \$163 tax ..
(455)	345	Comprehensive income
	\$ 3,732	
	\$ 7,578	=====

~~A significant portion of the foreign currency translation adjustment recorded for the three months ended March 31, 2005 was related to the appreciation of the U.S. dollar against the euro following the Company's acquisition of Newdeal Technologies, whose functional currency is the euro, on January 3, 2005.~~

~~7. NET INCOME PER SHARE~~

~~Basic and diluted net income per share was as follows:~~

Three Months Ended March 31,	2005	2004
(In thousands, except per share amounts) Basic net income per share:		
Net income		
\$ 8,443	\$ 7,438	Weighted average common shares outstanding
		30,561 29,704
	\$ 0.28	\$ 0.25
Diluted net income per share:		
Net income		
\$ 8,443	\$ 7,438	Add back: Interest expense and other income/(expense) related to convertible notes payable, net of tax
		544 520
	\$ 8,987	\$ 7,958
		Weighted average common shares outstanding
		30,561 29,704
		Effect of dilutive securities: Stock options
		1,069 1,155
		Shares issuable upon conversion of notes payable
		3,514 3,514
		Weighted average common shares for diluted earnings per share
		35,144 34,373
	\$ 0.26	\$ 0.23

~~Options outstanding at March 31, 2005 and 2004, respectively, to purchase approximately 42,000 and 35,000 shares of common stock were excluded from the computation of diluted net income per share for the three month periods ended March 31, 2005 and 2004 because their exercise price exceeded the average market price of the Company's common stock during the period.~~

~~In October 2004, the EITF reached a consensus on Issue 04-08 "The Effect of Contingently Convertible Instruments on Diluted Earnings per Share" that requires issuers of contingent convertible securities to account for these securities on an "if converted" basis pursuant to Statement of Financial Accounting Standards No. 128 "Earnings Per Share", in computing their diluted earnings per share whether or not the issuer's stock is above the contingent conversion price. The provisions of Issue 04-08 were applied on a retroactive basis, and this reduced previously reported diluted earnings per share by \$0.01 to \$0.23 in the three months ended March 31, 2004.~~

~~8. SEGMENT AND GEOGRAPHIC INFORMATION~~

~~Integra management reviews financial results and manages the business on an aggregate basis. Therefore, financial results are reported in a single operating segment, the development, manufacture and marketing of medical devices for use in neuro trauma, neurosurgery, reconstructive surgery and general surgery.~~

Revenues consisted of the following:

Three Months Ended March 31, (in
thousands) 2005 2004

Implant products

~~\$25,888 \$18,332~~ Instruments

~~22,527 16,043~~ Monitoring products

~~11,374~~

~~11,198~~ Private label products

~~6,010~~

~~5,862~~ Total product

~~revenues~~

~~65,799 51,435~~ Other revenues

~~40 1,008~~ Total revenues

~~\$65,839 \$52,443~~

Certain of the Company's products, including the DuraGen(R) Dural Graft Matrix products, NeuraGen(TM) Nerve Guide, INTEGRA(R) Dermal Regeneration Template, INTEGRA(TM) Bi-Layer Matrix Wound Dressing, and BioMend(R) Absorbable Collagen Membrane, contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food as well as pharmaceuticals and medical devices, are increasingly subject to scrutiny from the press and regulatory authorities. These products comprised 30% and 31% of total revenues in the three month periods ended March 31, 2005 and 2004, respectively. Accordingly, widespread public controversy concerning collagen products, new regulation, or a ban of the Company's products containing material derived from bovine tissue, could have a material adverse effect on the Company's current business or its ability to expand its business.

Total revenues by major geographic area are summarized below:

United

Asia Other

States

Europe

Pacific

Foreign

Total

(in
thousands)

Three

months

ended

March 31,

2005... \$

~~47,367~~ \$

~~12,762~~ \$

~~3,048~~ \$

~~2,662~~ \$

~~65,839~~

Three

months

ended

March 31,

2004... \$

~~41,394~~

~~7,248~~

~~1,829~~

~~1,972~~

~~52,443~~

9. COMMITMENTS AND CONTINGENCIES

Various lawsuits, claims and proceedings are pending or have been settled by the Company. The most significant of those are described below.

In July 1996, the Company filed a patent infringement lawsuit in the United States District Court for the Southern District of California (the "Trial

Court") against Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps, seeking damages and injunctive relief. The complaint charged, among other things, that the defendant Merck KGaA willfully and deliberately induced, and continues willfully and deliberately to induce, defendants Scripps Research Institute and Dr. Cheresh to infringe certain of the Company's patents. These patents are part of a group of patents granted to The Burnham Institute and licensed by Integra that are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid ("RGD") peptide sequence found in many extracellular matrix proteins. The defendants filed a countersuit asking for an award of defendants' reasonable attorney fees.

In March 2000, a jury returned a unanimous verdict in the Company's favor and awarded Integra \$15.0 million in damages, finding that Merck KGaA had willfully infringed and induced the infringement of our patents. The Trial Court dismissed Scripps and Dr. Cheresh from the case.

In October 2000, the Trial Court entered judgment in Integra's favor and against Merck KGaA in the case. In entering the judgment, the Trial Court also granted

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to the Company pre judgment interest of \$1.4 million, bringing the total award to \$16.4 million, plus post judgment interest. Merck KGaA filed various post trial motions requesting a judgment as a matter of law notwithstanding the verdict or a new trial, in each case regarding infringement, invalidity and damages. In September 2001, the Trial Court entered orders in favor of Integra and against Merck KGaA on the final post judgment motions in the case, and denied Merck KGaA's motions for judgment as a matter of law and for a new trial.

Merck KGaA and Integra each appealed various decisions of the Trial Court to the United States Court of Appeals for the Federal Circuit (the "Circuit Court"). In June 2003, the Circuit Court affirmed the Trial Court's finding that Merck KGaA had infringed our patents. The Circuit Court also held that the basis of the jury's calculation of damages was not clear from the trial record, and remanded the case to the Trial Court for further factual development and a new calculation of damages consistent with the Circuit Court's decision. Merck KGaA filed a petition for a writ of certiorari with the United States Supreme Court (the "Supreme Court") seeking review of the Circuit Court's decision, and the Supreme Court granted the writ in January 2005. Oral arguments before the United States Supreme Court were held in April 2005. We expect the Supreme Court to render a decision before the end of its current term.

In September 2004, the Trial Court ordered Merck KgaA to pay Integra \$6.4 million in damages, following the Circuit Court's order. Further enforcement of the Trial Court's order has been stayed pending the decision of the Supreme Court.

The Company has not recorded any gain in connection with this matter, pending final resolution and completion of the appeals process.

Three of the Company's French subsidiaries that were acquired from the neurosciences division of NMT Medical, Inc. received a tax reassessment notice from the French tax authorities seeking in excess of 1.7 million euros in back taxes, interest and penalties. NMT Medical, the former owner of these entities, has agreed to indemnify Integra against direct damages and liability arising from misrepresentations in connection with these tax claims. In April 2005, NMT Medical, Inc. negotiated a settlement agreement with the French authorities that will satisfy the outstanding tax assessments. This settlement will not have any impact on the Company's financial statements.

In addition to these matters, 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 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 the Company's 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.

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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 consolidated financial statements and the related notes thereto appearing elsewhere in this report and our consolidated financial statements for the year ended December 31, 2004 included in our Annual Report on Form 10-K.~~

~~This discussion and analysis contains forward looking statements that involve risks, uncertainties and assumptions. 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 below under the heading "Factors That May Affect Our Future Performance."~~

~~GENERAL~~

~~Integra develops, manufactures and markets medical devices for use in neuro-trauma, neurosurgery, reconstructive surgery and general surgery. Our business is organized into product groups and distribution channels. Our product groups include implants and other devices for use in surgical procedures, monitoring systems for the measurement of various parameters in tissue (such as pressure, temperature and oxygen), hand held and ultrasonic surgical instruments, and private label products that we manufacture for other medical device companies.~~

~~Our distribution channels include three sales organizations in the United States: one that we employ to call on neurosurgeons known as our Integra NeuroSciences(TM) sales organization, another employed to call on reconstructive surgeons and a third group that utilizes a network of third party distributors. Internationally, we combine resources across different sales channels in some cases with direct sales organizations in France, Germany, the United Kingdom and the Benelux region. Outside of these areas, we operate through a number of distributors that sell our products in over 90 countries. We invest substantial resources and management effort to develop our sales organizations, and we believe that we compete very effectively in this aspect of our business. We distribute private label products through strategic alliances.~~

~~We manufacture most of the implant, monitoring and private label products that we sell in various plants located in the United States, Puerto Rico, France, the United Kingdom and Germany. We also manufacture the ultrasonic surgical instruments and source most of our hand held surgical instruments through specialized third party vendors.~~

~~We believe that we have a particular advantage in the development, manufacture and sale of specialty tissue repair products derived from bovine collagen. We develop and build these products in our manufacturing facility in Plainsboro, New Jersey. Taken together, these products accounted for approximately 30% and 31% of total revenues in the three months ended March 31, 2005 and 2004, respectively.~~

~~We manage these multiple product groups and distribution channels on a centralized basis. Accordingly, we report our financial results under a single operating segment—the development, manufacturing and distribution of medical devices.~~

~~Our objective is to build a customer focused and profitable medical device company by developing or acquiring innovative medical devices and other products~~

~~to sell through our sales channels. Our strategy therefore entails substantial growth in product revenues both through internal means—through launching new and innovative products and selling existing products more intensively—and by acquiring existing businesses or already successful product lines.~~

~~We aim to achieve this growth in 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 tend to support the view that our profitability can grow for a period of years. These measurements include revenue growth, derived through acquisitions and products developed internally, gross margins on products revenues, which we hope to increase to more than 65% over a period of several years, operating margins, which we hope~~

~~to continually expand on as we leverage our existing infrastructure, and earnings per fully diluted share of common stock.~~

~~RESULTS OF OPERATIONS~~

~~Our strategy for growing our business includes the acquisition of complementary product lines and companies. Recent acquisitions (as discussed in Note 2 to our unaudited consolidated financial statements), may make our financial results for the three month period ended March 31, 2005 not directly comparable to those of the corresponding prior year period.~~

~~Net income for the three months ended March 31, 2005 was \$8.4 million, or \$0.26 per diluted share, as compared to net income of \$7.4 million, or \$0.23 per diluted share, for the three months ended March 31, 2004.~~

~~These amounts include the following costs associated with the closing of various facilities and related transitions, and acquisition and integration related costs:~~

Three Months Ended March 31, (in thousands) 2005 2004	
Inventory fair market value purchase accounting adjustments.....	\$ 269 \$ —
Acquisition and integration related costs, including costs associated with the closing of various facilities and related transitions and foreign dealer terminations	517
	—

~~We believe that, given our on-going, active strategy of seeking acquisitions, identifying such costs related to acquisitions and integrations provides useful information to measure the comparative performance of our business operations.~~

~~Revenues and Gross Margin on Product Revenues~~

Three Months Ended March 31, (in thousands) 2005 2004	
Implant products	\$25,888 \$18,332
Instruments	22,527 16,043
Monitoring products	11,374
Private label products	11,198 6,010
Total revenues	5,862
Other revenues	\$65,799 \$51,435
Total revenues	40 1,008
Cost of product revenues.....	\$65,839 \$52,443
Gross margin on total revenues.....	24,133 20,001
Gross margin as a percentage of total revenues.....	41,706 63% 62%

~~For the quarter ended March 31, 2005, total revenues increased 26% over the prior year to \$65.8 million. Domestic revenues increased \$6.0 million in 2005 to \$47.4 million, or 72% of total revenues, as compared to 79% of revenues in the first quarter ended March 31, 2004.~~

~~Sales of implant products and instruments, which reported a 41% and 40% increase, respectively, in sales over 2004, led our growth in revenues in 2005.~~

~~Rapid growth in the NeuraGen(TM) Nerve Guide, the INTEGRA(R) Dermal Regeneration Template and the INTEGRA(TM) Bilayer Matrix Wound Dressing products, and new sales of Newdeal products for the foot and ankle accounted for most of the increase in implant product revenues. Sales of our NeuraGen(TM) and Neurawrap(TM) products increased 96% over the prior year period. Sales of our dermal repair products, including the INTEGRA(R) Dermal Regeneration Template and the INTEGRA(TM) Bilayer Matrix Wound Dressing products, and the INTEGRA(TM) Matrix Wound Dressing, increased 56% over the first quarter of 2004. Newdeal product revenues of \$4.5 million met our expectations for the quarter. Sales of the NPH(TM) Low Flow Hydrocephalus Valve that we introduced in late 2004 also contributed to the growth in implant product revenues for the quarter. Our DuraGen(R) family of duraplasty products continued to grow, albeit at slower rates than in recent years.~~

~~Revenues from our instrument product lines increased principally as a result of increased sales of our JARIT surgical instrument line and from sales of the recently acquired MAYFIELD cranial stabilization product line, the ELEKTROTOM electrosurgery generators, and the SONOTOM(R) ultrasonic surgical aspirator product line.~~

~~Slower than expected acceptance of our LICOX(R) Brain Oxygen Monitoring Systems in the United States and a slow down in the growth of our drainage systems led to minimal year over year growth in monitoring product revenues. We expect that the launch of Integra's NeuroSensor(R) cerebral blood flow monitoring system later this year will improve the performance of this category.~~

~~Increased sales of our Absorbable Collagen Sponge that we supply for use in Medtronic's INFUSE(TM) bone graft product offset the decrease in Signature Technologies revenues following the expiration of our supply contract in June 2004.~~

~~Revenues from product lines acquired since the beginning of the second quarter of 2004 accounted for \$9.4 million of the \$14.4 million increase in product revenues over the prior year period. Changes in foreign currency exchange rates also accounted for \$0.4 million of the increase in product revenues.~~

~~We have generated our recent product revenue growth through acquisitions, new product launches and increased direct sales and marketing efforts both domestically and in Europe. We expect that our future revenue growth will be driven by our expanded domestic sales force, the continued implementation of our direct sales strategy in Europe and from internally developed and acquired products. We also intend to continue to acquire businesses that complement our existing businesses and products.~~

~~Our gross margin on total revenues was 63% and 62% in the quarter ended March 31, 2005 and March 31, 2004 respectively. The current quarter's gross margin benefited from strong growth in our higher margin products sold during the quarter, including the Newdeal product line. Inventory fair market value purchase accounting adjustments totaling \$269,000 reduced reported gross margins by 1 percentage point in the first quarter of 2005.~~

~~Other Operating Expenses:~~

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

Three Months Ended March 31, (in thousands) 2005 2004	
Research and development	
5% 5% Selling, general and administrative	
36% 32%	

~~Total other operating expenses, which exclude cost of product revenue but include amortization, increased 39% to \$28.8 million in the first quarter of 2005, compared to \$20.7 million in the first quarter of 2004.~~

~~Research and development expenses increased approximately \$0.5 million to \$3.4 million in the first quarter of 2005. Expenses increased due to higher spending on research and clinical activities related to our absorbable implant technology products. In 2005, we expect our research and development expenses as a percentage of total revenues to remain consistent with 2004 as we increase expenditures on research and clinical activities directed towards expanding the indications for use of our absorbable implant technology products, including a multi-center clinical trial suitable to support an application to the FDA for approval of the DuraGen Plus(TM) Adhesion Barrier Matrix product in the United States that was initiated in the first quarter of 2005.~~

~~Sales, general, and administrative expenses increased 41% over the prior year period to \$23.9 million. In 2005, we continue to build our direct sales and marketing organizations around all three direct selling platforms and have increased corporate staff to support the recent growth in our business and integrate acquired businesses. Additionally, we have recently made significant investments in our infrastructure with the implementation of a new enterprise business system and the relocation and expansion of our distribution capabilities through a third party service provider.~~

~~Amortization expense increased in the first quarter of 2005 as a result of amortization of intangible assets from recent acquisitions.~~

~~Non-Operating Income And Expenses~~

~~Interest expense is related to the \$120 million of contingent convertible subordinated notes we have outstanding and a related interest rate swap agreement. Our reported interest expense includes \$0.2 million of non cash amortization of debt issuance costs. Debt issuance costs totaled \$4.0 million and are being amortized using the straight line method over the five year term of the notes.~~

~~We will pay additional interest ("Contingent Interest") on our convertible notes under certain conditions. The fair value of this Contingent Interest obligation is marked to its fair value at each balance sheet date, with changes in the fair value recorded to interest expense. In the first quarter of 2005 and 2004, the changes in the estimated fair value of the Contingent Interest obligation were not significant.~~

~~In August 2003, we entered into an interest rate swap agreement with a \$50.0 million notional amount to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of our fixed rate convertible notes. The interest rate swap agreement qualifies as a fair value hedge under SFAS No. 133, as amended "Accounting for Derivative Instruments and Hedging Activities". The net amount to be paid or received under the interest rate swap agreement is recorded as a component of interest expense. Interest expense associated with the interest rate swap for the three months ended March 31, 2005 was not significant. Interest expense for the three months ended March 31, 2004 included a \$210,000 benefit associated with the interest rate swap.~~

~~The net fair value of the interest rate swap at December 31, 2004 was \$1.4 million. At March 31, 2005, the net fair value of the interest rate swap increased \$0.7 million to \$2.1 million and this amount is included in other liabilities. In connection with this fair value hedge transaction, during the~~

~~first quarter of 2005, we recorded a \$0.8 million net increase in the carrying value of our convertible notes. The net difference between changes in the fair value of the interest rate swap and the contingent convertible notes represents the ineffective portion of the hedging relationship, and this amount is recorded in other income.~~

~~Our net other expense increased by \$76,000 in the first quarter of 2005 and included a \$204,000 loss associated with the settlement of a foreign currency collar, which was used to reduce our exposure to fluctuations in the exchange rate between the euro and the US dollar as a result of our commitment to acquire Newdeal Technologies for 38.3 million euros (\$51.9 million) in January 2005.~~

~~Income tax expense was approximately 34.5% and 36.8% of income before income taxes for the first quarters of 2005 and 2004, respectively. Income tax expense for the first quarters of 2005 and 2004 included a deferred income tax provision of \$3.1 million and \$3.2 million, respectively. The decrease in the effective income tax rate in 2005 resulted primarily from the benefits received from the recent reorganization of our European assets.~~

~~International Operations~~

~~Because we have operations based in Europe and we generate revenues and incur operating expenses in euros and British pounds, we have currency exchange risk with respect to those foreign currency denominated revenues or expenses.~~

~~In the first quarter of 2005, the cost of products we manufactured in our European facilities or purchased in foreign currencies exceeded our foreign currency denominated revenues. We expect this imbalance to continue. We currently do not hedge our exposure to foreign currency risk. Accordingly, a weakening of the dollar against the euro and British pound could negatively affect future gross margins and operating margins. We will continue to assess the potential effects that changes in foreign currency exchange rates could have on our business. If we believe this potential impact presents a significant risk to our business, we may enter into derivative financial instruments to mitigate this risk.~~

~~Additionally, 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 may have an impact on the demand for our products in foreign countries.~~

~~Our sales to foreign markets may be affected by local economic conditions, regulatory or political considerations, the effectiveness of our sales representatives and distributors, local competition, and changes in local medical practice.~~

~~Relationships with customers and effective terms of sale frequently vary by country, often with longer term receivables than are typical in the United States.~~

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~~Total revenues by major geographic area are summarized below:~~

~~United
Asia-Other
States
Europe
Pacifie
Foreign
Total~~

~~(in
thousands)
Three
months
ended
March 31,
2005... \$
47,367 \$
12,762 \$
3,048 \$
2,662 \$~~

65,839
Three
months
ended
March 31,
2004...
41,394
7,248
1,829
1,972
52,443

~~For the three months ended March 31, 2005, revenues from customers outside the United States totaled \$18.5 million, or 28% of total revenues, of which approximately 69% were to European customers. Of this amount, \$14.3 million was generated in foreign currencies primarily by our subsidiaries in the Europe.~~

~~For the three months ended March 31, 2004, revenues from customers outside the United States totaled \$11.0 million, or 21% of total revenues, of which approximately 66% were to European customers. Of this amount, \$8.1 million was generated in foreign currencies by our subsidiaries in Europe.~~

~~LIQUIDITY AND CAPITAL RESOURCES~~

~~Cash and Marketable Securities~~

~~At March 31, 2005, we had cash, cash equivalents and current and non-current investments totaling approximately \$157.9 million. Our investments consist almost entirely of highly liquid, interest bearing debt securities.~~

~~At March 31, 2005, we had \$3.3 million of cash pledged as collateral in connection with our interest rate swap agreement.~~

~~Cash Flows~~

~~Cash provided by operations has recently been and is expected to continue to be our primary means of funding existing operations and capital expenditures. We have generated positive operating cash flows on an annual basis, including \$34.8 million in 2003, \$39.0 million in 2004, and \$13.2 million of operating cash flows in the three months ending March 31, 2005. Operating cash flows for the quarter ending March 31, 2004, were \$10.9 million.~~

~~Our principal uses of funds during the three month period ended March 31, 2005 were \$49.3 million for acquisition consideration, net of cash acquired, \$0.2 million for purchases of investments, net of maturities and sales, and \$2.8 million for purchases of property and equipment. In addition to the \$13.2 million in operating cash flows for the three months ended March 31, 2005, we received \$2.3 million from the issuance of common stock through the exercise of stock options during the period.~~

~~Based on our current unused net operating loss carryforward position and various other future potential tax deductions, we expect our operating cash flows to continue to benefit from actual cash tax payments being lower than our effective book income tax rate for at least the next two years.~~

~~Working Capital~~

~~At March 31, 2005 and December 31, 2004, working capital was \$174.0 million and \$192.0 million, respectively. The decrease in working capital was primarily related to the cash used in the Newdeal acquisition in January of 2005.~~

~~We expect our days on hand in accounts receivable and inventory to return to historic trend levels during the second half of 2005.~~

~~Debt~~

~~We have outstanding \$120.0 million of 2 1/2% contingent convertible subordinated notes due 2008. We are obligated to pay \$3.0 million of interest per year on the notes and to repay their principal amount on March 15, 2008, if the notes are not converted into common stock before that date. We will also pay contingent interest on the notes if, at thirty days prior to maturity, Integra's common stock price is greater than \$37.56, subject to certain conditions.~~

~~We also have outstanding an interest rate swap agreement with a \$50 million notional amount to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of the convertible notes. We receive a 2 1/2% fixed rate from the counterparty, payable on a semi-annual~~

~~basis, and pay to the counterparty a floating rate based on 3-month LIBOR minus 35 basis points, payable on a quarterly basis. The interest rate swap agreement terminates on March 15, 2008, subject to early termination upon the occurrence of certain events, including redemption or conversion of the contingent convertible notes.~~

~~We also have outstanding long-term indebtedness totaling \$0.5 million related to the recently acquired Newdeal business.~~

~~Share Repurchase Plan~~

~~In May 2005, our Board of Directors authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed \$40 million through December 31, 2006. We may repurchase no more than 1.5 million shares under this program. Shares may be purchased either in the open market or in privately negotiated transactions.~~

~~Dividend Policy~~

~~We have not paid any cash dividends on our common stock since our formation. 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.~~

~~Requirements and Capital Resources~~

~~We believe that our cash and marketable securities are sufficient to finance our operations and capital expenditures in the near term. We expect to invest approximately \$3.5 million in 2005 associated with the continued worldwide implementation of our new enterprise business software. Additionally, we have agreed to pay the sellers of Newdeal Technologies SA up to an additional 1,250,000 euros if each of the sellers continues his employment with Integra through January 3, 2006.~~

~~Given the significant level of liquid assets and our objective to grow by acquisition and alliances, our financial position could change significantly if we were to complete a business acquisition by utilizing a significant portion of our liquid assets.~~

~~Currently, we do not have any existing borrowing capacity or other credit facilities in place to raise significant amounts of capital if such a need arises.~~

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~~Contractual Obligations and Commitments~~

~~Under certain agreements, we are required to make payments based on sales levels of certain products or if specific development milestones are achieved.~~

~~OTHER MATTERS~~

~~RECENTLY ISSUED ACCOUNTING STANDARDS AND OTHER MATTERS~~

~~In November 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 151, "Inventory Costs an amendment of ARB No. 43, Chapter 4" (Statement 151), which is effective beginning January 1, 2006. Statement 151 requires that abnormal amounts of idle facility expense, freight, handling costs and wasted material be recognized as current period charges. Statement 151 also requires that the allocation of fixed production overhead be based on the normal capacity of the production facilities. We are currently assessing the potential effect that Statement 151 could have on our financial position or results of operations.~~

~~In March 2004, the FASB Emerging Issue Task Force (EITF) reached a consensus on Issue 03-01, "The Meaning of Other Than Temporary Impairment and Its Application to Certain Investments". Issue 03-01 provides guidance regarding recognition and measurement of unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, "Accounting for Certain Investments in Debt and Equity Securities". The application of certain paragraphs covering the measurement provisions of Issue 03-01 have been deferred pending the issuance of a final FASB Staff Position providing implementation guidance on Issue 03-01. The disclosures were effective in annual financial statements for fiscal years ending after December 15, 2003. Management is currently assessing the impact that the recognition and measurement provisions of Issue 03-01 could have on our financial statements.~~

~~The American Jobs Creation Act of 2004 (the "Act") was signed into law in~~

~~October 2004 and has several provisions that may impact our income taxes in the future, including the repeal of the extraterritorial income exclusion and a deduction related to qualified production activities taxable income. The FASB proposed that the qualified production activities deduction is a special deduction and will have no impact on deferred taxes existing at the enactment date. Rather, the impact of this deduction will be reported in the period in which the deduction is claimed on our tax return. We are currently evaluating the impact of the FASB guidance related to qualified production activities on our effective tax rate in future periods.~~

~~In December 2004, the FASB issued Statement No. 123 (revised 2004), "Share Based Payment," which is a revision of Statement No. 123, "Accounting for Stock Based Compensation." Statement 123(R) replaces APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends Statement No. 95, "Statement of Cash Flows." Statement 123(R) requires all share based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value. Pro forma footnote disclosure will no longer be an alternative to financial statement recognition.~~

~~Statement 123(R) must be adopted no later than January 1, 2006. Statement 123(R) permits companies to adopt its requirements using either the "modified~~

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~~prospective" method or the "modified retrospective" method. Management is currently evaluating the potential impact of Statement 123(R) on our consolidated financial position and results of operations and the alternative adoption methods.~~

~~FACTORS THAT MAY AFFECT OUR FUTURE PERFORMANCE~~

~~Our Operating Results May Fluctuate.~~

~~Our operating results, including components of operating results, such as gross margin on product sales, may fluctuate from time to time, which could affect our stock price. Our operating results have fluctuated in the past and can be expected to fluctuate from time to time in the future. Some of the factors that may cause these fluctuations include:~~

- ~~the impact of acquisitions;~~
- ~~the timing of significant customer orders;~~
- ~~market acceptance of our existing products, as well as products in development;~~
- ~~the timing of regulatory approvals;~~
- ~~the timing of payments received and the recognition of those payments as revenue under collaborative arrangements and other alliances;~~
- ~~changes in the rate of exchange between the U.S. dollar, the euro and the British pound;~~
- ~~expenses incurred and business lost in connection with product field corrections or recalls;~~
- ~~our ability to manufacture our products efficiently; and~~
- ~~the timing of our research and development expenditures.~~

~~Non-Cash Compensation Charges May Affect Our Future Earnings.~~

~~In December 2004, the Financial Accounting Standards Board issued Statement No. 123 (revised 2004), "Share Based Payment," which is a revision of Statement No. 123, "Accounting for Stock Based Compensation." Statement 123(R) replaces APB Opinion No. 25, "Accounting for Stock Issued to Employees". Statement 123(R) requires all share based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value.~~

~~Statement 123(R) must be adopted no later than January 1, 2006. For purposes of disclosing pro forma financial results in our financial statements as if compensation cost for our stock option plans had been determined based on the fair value at the grant consistent with the provisions of Statement No. 123, we historically estimated the fair value of stock options granted prior to October 1, 2004 using the Black Scholes valuation model. However, we estimated the pro forma additional compensation expense related to all options granted on or after October 1, 2004 using a binomial distribution model. Management believes that the binomial distribution model is preferable to the Black Scholes model because the binomial distribution model is a more flexible model that considers the impact of non transferability, vesting and forfeiture provisions in the valuation of employee stock options. Because Statement 123(R) prohibits pro forma footnote disclosure as an alternative to financial statement recognition, management is currently evaluating the potential impact that Statement 123(R) will have on our future results of operations. Previous estimates of option values using the Black Scholes method may not be indicative of results from applying the binomial distribution model for valuing future option grants.~~

~~The Industry And Market Segments in Which We Operate Are Highly Competitive, And We May Be Unable to Compete Effectively with Other Companies.~~

~~In general, the medical technology industry is characterized by intense competition. We compete with established medical technology and pharmaceutical companies. Competition also comes from early stage companies that have~~

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~~alternative technological solutions for our primary clinical targets, as well as universities, research institutions and other non-profit entities. Many of our competitors have access to greater financial, technical, research and development, marketing, manufacturing, sales, distribution services and other resources than we do. Our competitors may be more effective at implementing their technologies to develop commercial products.~~

~~Our competitive position will depend on our ability to achieve market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory approval for products under development and obtain patent protection. We may need to develop new applications for our products to remain competitive. Technological advances by one or more of our current or future competitors could render our present or future products obsolete or uneconomical. Our future success will depend upon our ability to compete effectively against current technology as well as to respond effectively to technological advances. Competitive pressures could adversely affect our profitability. For example, two of our largest competitors have recently introduced an onlay dural graft matrix, and other companies may be preparing to introduce similar products. The introduction of such products could reduce the sales, growth in sales and profitability of our duraplasty products, including our DuraGen(R), DuraGen Plus(TM), Suturable DuraGen(TM) and EnDura(TM) product lines, which are among our largest and fastest growing products.~~

~~Our largest competitors in the neurosurgery markets are the Medtronic Neurotechnologies division of Medtronic, Inc., the Codman division of Johnson & Johnson, the Aesculap division of B. Braun and the Valleylab division of Tyco International Ltd. In addition, many of our product lines compete with smaller specialized companies or larger companies that do not otherwise focus on neurosurgery. Our reconstructive surgery business is small compared to its principal competitors, which include major medical device and wound care companies such as Smith and Nephew plc, LifeCell Corporation and Organogenesis Inc., as well as companies focused on foot and ankle surgeons including Wright Medical Group, Inc., the DePuy division of Johnson & Johnson and Synthes, Inc. Our private label products face diverse and broad competition, depending on the market addressed by the product. Finally, in certain cases our products compete primarily against medical practices that treat a condition without using a device, rather than any particular product, such as autograft tissue as an alternative for the INTEGRA(R) Dermal Regeneration Template, our duraplasty products and the NeuraGen(TM) Nerve Guide.~~

~~Our Current Strategy Involves Growth Through Acquisitions, Which Requires Us To Incur Substantial Costs And Potential Liabilities For Which We May Never Realize The Anticipated Benefits.~~

~~In addition to internal growth, our current strategy involves growth through acquisitions. Since 1999, we have acquired 20 businesses or product lines at a total cost of approximately \$213 million.~~

~~We may be unable to continue to implement our growth strategy, and our strategy ultimately may be unsuccessful. A significant portion of our growth in revenues has resulted from, and is expected to continue to result from, the acquisition of businesses complementary to our own. We engage in evaluations of potential acquisitions and are in various stages of discussion regarding possible acquisitions, certain of which, if consummated, could be significant to us. Any potential acquisitions may result in material transaction expenses, increased interest and amortization expense, increased depreciation expense and increased operating expense, any of which could have a material adverse effect on our operating results. As we grow by acquisitions, we must integrate and manage the new businesses to realize economies of scale and control costs. In addition, acquisitions involve other risks, including diversion of management resources~~

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~~otherwise available for ongoing development of our business and risks associated with entering new markets with which our marketing and sales force has limited experience or where experienced distribution alliances are not available. Our future profitability will depend in part upon our ability to develop further our resources to adapt to these new products or business areas and to identify and enter into satisfactory distribution networks. We may not be able to identify suitable acquisition candidates in the future, obtain acceptable financing or consummate any future acquisitions. If we cannot integrate acquired operations, manage the cost of providing our products or price our products appropriately,~~

~~our profitability could suffer. In addition, as a result of our acquisitions of other healthcare businesses, we may be subject to the risk of unanticipated business uncertainties, regulatory matters or legal liabilities relating to those acquired businesses for which the sellers of the acquired businesses may not indemnify us. Future acquisitions may also result in potentially dilutive issuances of securities.~~

~~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.~~

~~Our research and development activities and the manufacturing, labeling, distribution and marketing of our existing and future products are subject to regulation by numerous governmental agencies in the United States and in other countries. The Food and Drug Administration (FDA) and comparable agencies in other countries impose mandatory procedures and standards for the conduct of clinical trials and the production and marketing of products for diagnostic and human therapeutic use.~~

~~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 full of uncertainties. 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. 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. In addition, for products with an approved PMA, the FDA requires annual reports and may require post approval surveillance programs to monitor the products' safety and effectiveness. Results of post approval programs may limit or expand the further marketing of the product.~~

~~Another risk of application to the FDA relates to the regulatory classification of new products or proposed new uses for existing products. In the filing of each application, we make a legal 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 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.~~

~~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.~~

~~The FDA and foreign regulatory authorities require that our products be manufactured according to rigorous standards. These regulatory requirements may significantly increase our production or purchasing costs and may 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 may mean that even if we develop promising new products, we may not be able to produce them profitably, as a result of delays and additional capital investment costs. Manufacturing facilities, both international and domestic, are also subject to inspections by or under the authority of the FDA. In addition, failure to comply with applicable regulatory requirements could subject us to enforcement action, including product seizures, recalls, withdrawal of clearances or approvals, restrictions on or injunctions against marketing our product or products based on our technology, and civil and criminal penalties.~~

~~We are also subject to the regulatory requirements of countries outside of the United States where we do business. For example, Japan is in the process of reforming its medical device regulations. A recent amendment to Japan's Pharmaceutical Affairs Law went into effect on April 1, 2005. New regulations and requirements exist for obtaining approval of medical devices, including new requirements governing the conduct of clinical trials, the manufacturing of products and the distribution of products in Japan. Significant resources also may be needed to comply with the extensive auditing of all manufacturing facilities of our company and our vendors by the Ministry of Health, Labor and Welfare in Japan to comply with the amendment to the Pharmaceutical Affairs Law. These new regulations may affect our ability to obtain approvals of new products as well as maintain the certain businesses in Japan. Sales in Japan accounted~~

~~for approximately \$3.1 million of our revenues in 2004.~~

~~Certain Of Our Products Contain Materials Derived From Animal Sources And May Become Subject To Additional Regulation.~~

~~Certain of our products, including the DuraGen(R) Dural Graft Matrix, DuraGen Plus(TM) Dural Regeneration Matrix, Suturable DuraGen(TM) Dural Regeneration Matrix and DuraGen Plus(TM) Adhesion Barrier Matrix products, the NeuraGen(TM) Nerve Guide, the NeuraWrap(TM) Nerve Protector, the INTEGRA(R) Dermal Regeneration Template, the INTEGRA(TM) Bilayer Matrix and INTEGRA(TM) Matrix Wound Dressing, the Helistat(R)/Helitene(R) Absorbable Collagen Hemostatic Agents, our Absorbable Collagen Sponges, the CollaCote(R), CollaTape(R) and CollaPlug(R) Absorbable Wound Dressings and the BioMend(R) and BioMend(R) Extend Absorbable Collagen Membranes, contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food as well as pharmaceuticals and medical devices, are increasingly subject to scrutiny in the press and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans via those materials. This public scrutiny has been particularly acute in Japan and Western Europe with respect to products derived from cattle, because of concern that materials infected with the agent that causes bovine spongiform encephalopathy, otherwise known as BSE or mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt Jakob Disease, an ultimately fatal disease with no known cure. Recent cases of BSE in cattle discovered in Canada and the United States have increased awareness of the issue in North America.~~

~~We take great care to provide that our products are safe and free of agents that can cause disease. In particular, the collagen used in the manufacture of our products is derived only from the deep flexor tendon of cattle from the United States that are less than 24 months old. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon, the sole source of our collagen, is in the lowest risk category for BSE transmission (the same category as milk, for example), and is therefore considered to have a negligible risk of containing the agent that causes BSE (an improperly folded protein known as a prion). Nevertheless, products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for prion transmission. Significant new regulation, or a ban of our products, could have a material adverse effect on our current business or our ability to expand our business.~~

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~~In addition, we have been notified that Japan has issued new regulations regarding medical devices that contain tissue of animal origin. Among other regulations, Japan may require that the tendon used in the manufacture of medical devices sold in Japan originate in a country that has never had a case of BSE. Currently, we purchase our tendon from the United States and have qualified a source of tendon from New Zealand, a country which has never had a case of BSE. If we cannot continue to qualify a source of tendon from New Zealand or another country that has never had a case of BSE, we will not be permitted to sell our collagen hemostatic agents and products for oral surgery in Japan. We do not currently sell our dural or skin repair products in Japan.~~

~~Lack Of Market Acceptance For Our Products Or Market Preference For Technologies That Compete With Our Products Could Reduce Our Revenues And Profitability.~~

~~We cannot be certain that our current products or any other products that we may develop or market will achieve or maintain market acceptance. Certain of the medical indications that can be treated by our devices can also be treated by other medical devices or by medical practices that do not include a device. The medical community widely accepts many alternative treatments, and certain of these other treatments have a long history of use. For example, the use of autograft tissue is a well established means for repairing the dermis, and it competes for acceptance in the market with the INTEGRA(R) Dermal Regeneration Template.~~

~~We cannot be certain that our devices and procedures will be able to replace those established treatments or that either physicians or the medical community in general will accept and utilize our devices or any other medical products that we may develop. For example, we cannot be certain that the medical community will accept the NeuraGen(TM) Nerve Guide over conventional microsurgical techniques for connecting severed peripheral nerves.~~

~~In addition, our future success depends, in part, on our ability to develop additional products. Even if we determine that a product candidate has medical benefits, the cost of commercializing that product candidate may be too high to justify development. Competitors may develop products that are more effective, cost less or are ready for commercial introduction before our products. For~~

~~example, our sales of shunt products could decline if neurosurgeons increase their use of programmable valves and we fail to introduce a competitive product, or our sales of certain catheters may be adversely affected by the recent introduction by other companies of catheters that contain anti-microbial agents intended to reduce the incidence of infection after implantation. If we are unable to develop additional commercially viable products, our future prospects could be adversely affected.~~

~~Market acceptance of our products depends on many factors, including our ability to convince prospective collaborators and customers that our technology is an attractive alternative to other technologies, to manufacture products in sufficient quantities and at acceptable costs, and to supply and service sufficient quantities of our products directly or through our distribution alliances. In addition, limited funding available for product and technology acquisitions by our customers, as well as internal obstacles to customer approvals of purchases of our products, could harm acceptance of our products. The industry is subject to rapid and continuous change arising from, among other things, consolidation and technological improvements. One or more of these factors may vary unpredictably, which could materially adversely affect our competitive position. We may not be able to adjust our contemplated plan of development to meet changing market demands.~~

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~~Our Intellectual Property Rights May Not Provide Meaningful Commercial Protection For Our Products, Which Could Enable Third Parties To Use Our Technology Or Very Similar Technology And Could Reduce Our Ability To Compete In The Market.~~

~~Our ability to compete effectively depends in part, on our ability to maintain the proprietary nature of our technologies and manufacturing processes, which includes the ability to obtain, protect and enforce patents on our technology and to protect our trade secrets. We own or have licensed patents that cover aspects of certain of our product lines. However, you should not rely on our patents to provide us with any significant competitive advantage. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. Competitors may develop products similar to ours that our patents do not cover. In addition, our current and future patent applications may not result in the issuance of patents in the United States or foreign countries. Further, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications usually takes from 18 to 24 months.~~

~~Our Competitive Position Depends, In Part, Upon Unpatented Trade Secrets Which We May Be Unable To Protect.~~

~~Our competitive position also depends upon unpatented trade secrets. Trade secrets are difficult to protect. We cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, that our trade secrets will not be disclosed or that we can effectively protect our rights to unpatented trade secrets.~~

~~In an effort to protect our trade secrets, we require our employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements provide that, except in specified circumstances, all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information.~~

~~Our Success Will Depend Partly On Our Ability To Operate Without Infringing Or Misappropriating The Proprietary Rights Of Others.~~

~~We may be sued for infringing the intellectual property rights of others. In addition, we may find it necessary, if threatened, to initiate a lawsuit seeking a declaration from a court that we do not infringe the proprietary rights of others or that their rights are invalid or unenforceable. If we do not prevail in any litigation, in addition to any damages we might have to pay, we would be required to stop the infringing activity or obtain a license for the proprietary rights involved. Any required license may be unavailable to us on acceptable terms, or at all. In addition, some licenses may be nonexclusive and allow our competitors to access the same technology we license. If we fail to obtain a required license or are unable to design our product so as not to infringe on the proprietary rights of others, we may be unable to sell some of our products, which could have a material adverse effect on our revenues and profitability.~~

~~It May Be Difficult To Replace Some Of Our Suppliers.~~

~~Outside vendors, some of whom are sole source suppliers, provide key components and raw materials used in the manufacture of our products. Although we believe that alternative sources for many of these components and raw materials are available, any supply interruption in a limited or sole source component or raw material could harm our ability to manufacture our products until a new source of supply is identified and qualified. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired. We believe that these factors are most likely to affect the following products that we manufacture:~~

~~_____ our collagen based products, such as INTEGRA(R) Dermal Regeneration
_____ Template, DuraGen(R) Dural Graft Matrix, DuraGen Plus(TM) Dural
_____ Regeneration and Suturable DuraGen(TM) Dural Regeneration Matrix
_____ products, and our Absorbable Collagen Sponges;
_____ our products made from silicone, such as our neurosurgical shunts and
_____ drainage systems and hemodynamic shunts; and
_____ products which use
_____ many different electronic parts from numerous suppliers, such as our
_____ Camino(R), Ventrrix(R) and NeuroSensor(TM) lines of intracranial
_____ monitors and catheters.~~

~~If we were suddenly unable to purchase products from one or more of these companies, we could need a significant period of time to qualify a replacement, and the production of any affected products could be disrupted. While it is our policy to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials.~~

~~If Any Of Our Manufacturing Facilities Were Damaged And/Or Our Manufacturing Or Business Processes Interrupted, We Could Experience Lost Revenues And Our Business Could Be Seriously Harmed.~~

~~We manufacture our products in a limited number of facilities. Damage to our manufacturing, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease development and manufacturing of some or all of our products. In particular, our San Diego, California facility that manufactures our Camino(R) and Ventrrix(R) product line is as susceptible to earthquake damage, wildfire damage and power losses from electrical shortages as are other businesses in the Southern California area. Our silicone manufacturing plant in Anasco, Puerto Rico is vulnerable to hurricane damage. Although we maintain property damage and business interruption insurance coverage on these facilities, we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs.~~

~~In addition, we are implementing in several stages over several years an enterprise business system for use in all of our facilities. This system will replace several systems on which we now rely. We have outsourced our product distribution function in the United States and are also planning to outsource our European product distribution function. A delay or other problem with the system or in our implementation schedule for either of these initiatives could have a material adverse effect on our operations.~~

~~We May Be Involved In Lawsuits To Protect Or Enforce Our Intellectual Property Rights, Which May Be Expensive.~~

~~To protect or enforce our intellectual property rights, we may have to initiate legal proceedings, such as infringement suits or interference proceedings, against third parties. Intellectual property litigation is costly, and, even if we prevail, the cost of that litigation could affect our profitability. In addition, litigation is time consuming and could divert management attention and resources away from our business. We may also provoke these third parties to assert claims against us.~~

~~We Are Exposed To A Variety Of Risks Relating To Our International Sales And Operations, Including Fluctuations In Exchange Rates, Local Economic Conditions And Delays In Collection Of Accounts Receivable.~~

~~We generate significant revenues outside the United States in euros, British pounds and in U.S. dollar denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. For those foreign customers who purchase our products in U.S. dollars, currency fluctuations between the U.S. dollar and the currencies in which those customers do business may have an impact on the demand for our products in foreign countries where the U.S. dollar has increased in value compared to the local currency.~~

~~Because we have operations based in Europe and we generate revenues and incur operating expenses in euros and British pounds, we experience currency exchange risk with respect to those foreign currency denominated revenues and expenses. In 2003 and 2004, the cost of products we manufactured in our European facilities or purchased in foreign currencies exceeded our foreign currency denominated revenues. We expect this imbalance to continue. Accordingly, a further weakening of the dollar against the euro and British pound could negatively affect future gross margins and operating margins.~~

~~Currently, we do not use derivative financial instruments to manage operating foreign currency risk. As the volume of our business transacted in foreign currencies increases, we will continue to assess the potential effects that changes in foreign currency exchange rates could have on our business. If we believe that this potential impact presents a significant risk to our business, we may enter into derivative financial instruments to mitigate this risk.~~

~~In general, we cannot predict the consolidated effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates.~~

~~Our sales to foreign markets also may be affected by local economic conditions, legal, regulatory or political considerations, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice. Relationships with customers and effective terms of sale frequently vary by country, often with longer term receivables than are typical in the United States.~~

~~Changes In The Health Care Industry May Require Us To Decrease The Selling Price For Our Products Or May Reduce The Size Of The Market For Our Products, Either Of Which Could Have A Negative Impact On Our Financial Performance.~~

~~Trends toward managed care, health care cost containment and other changes in government and private sector initiatives in the United States and other countries in which we do business are placing increased emphasis on the delivery of more cost effective medical therapies that could adversely affect the sale and/or the prices of our products. For example:~~

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~~major third party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and private health care insurers, have substantially revised their payment methodologies, which has resulted in stricter standards for reimbursement of hospital charges for certain medical procedures;~~
~~Medicare, Medicaid and private health care insurer cutbacks could create downward price pressure on our products;~~
~~numerous legislative proposals have been considered that would result in major reforms in the U.S. health care system that could have an adverse effect on our business;~~
~~there has been a consolidation among health care facilities and purchasers of medical devices in the United States who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;~~
~~we are party to contracts with group purchasing organizations that require us to discount our prices for certain of our products and limit our ability to raise prices for certain of our products, particularly surgical instruments;~~
~~there is economic pressure to contain health care costs in international markets;~~
~~there are proposed and existing laws, regulations and industry policies in domestic and international markets regulating the sales and marketing practices and the pricing and profitability of companies in the health care industry; and~~
~~there have been initiatives by third party payors to challenge the prices charged for medical products that could affect our ability to sell products on a competitive basis.~~

~~Both the pressures to reduce prices for our products in response to these trends and the decrease in the size of the market as a result of these trends could adversely affect our levels of revenues and profitability of sales.~~

~~Regulatory Oversight Of The Medical Device Industry Might Affect The Manner In Which We May Sell Medical Devices~~

~~There are laws and regulations that regulate the means by which companies in the health care industry may market their products to health care professionals and may compete by discounting the prices of their products. 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.~~

~~In January 2004, ADVAMED, the principal U.S. trade association for the medical device industry, put in place 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 ADVAMED Code, and we provide routine training to our sales and marketing personnel on our policies regarding sales and marketing practices. Nevertheless, we believe that the sales and marketing practices of our industry will be subject to increased scrutiny from government agencies.~~

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~~Our Private Label Business Depends Significantly On Key Relationships With Third Parties, Which We May Be Unable To Establish And Maintain.~~

~~Our private label business depends in part on our entering into and maintaining collaborative or alliance agreements with third parties concerning product marketing, as well as research and development programs. Our most important alliance is our agreement with the Wyeth BioPharma division of Wyeth for the development of collagen matrices to be used in conjunction with Wyeth BioPharma's recombinant bone protein, a protein that stimulates the growth of bone in humans. Termination of any of our alliances would require us to develop other means to distribute the affected products and could adversely affect our expectations for the growth of private label products.~~

~~We May Have Significant Product Liability Exposure And Our Insurance May Not Cover All Potential Claims.~~

~~We are exposed to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We may not be able to obtain insurance for the potential liability on acceptable terms with adequate coverage or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Our insurance may not be renewed at a cost and level of coverage comparable to that then in effect.~~

~~We Are Subject To Other Regulatory Requirements Relating To Occupational Health And Safety And The Use Of Hazardous Substances Which May Impose Significant Compliance Costs On Us.~~

~~We are subject to regulation under federal and state laws regarding occupational health and safety, laboratory practices and the use, handling and disposal of toxic or hazardous substances. Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. Although we believe that our safety procedures for handling and disposing of those materials comply with the standards prescribed by the applicable laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any related liability could exceed the limits or fall outside the coverage of our insurance and could exceed our resources. We may not be able to maintain insurance on acceptable terms or at all. We may incur significant costs to comply with environmental laws and regulations in the future. We may also be subject to other present and possible future local, state, federal and foreign regulations.~~

~~The Loss Of Key Personnel Could Harm Our Business.~~

~~We believe our success depends on the contributions of a number of our key~~

~~personnel, including Stuart M. Essig, our President and Chief Executive Officer. If we lose the services of key personnel, those losses could materially harm our business. We maintain key person life insurance on Mr. Essig.~~

~~FORWARD-LOOKING STATEMENTS~~

~~We have made statements in this report, including statements under "Management's Discussion and Analysis of Financial Condition and Results of Operations" 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. These forward looking statements are subject to a number of risks, uncertainties and assumptions about the Company, including those described under "Factors that May Affect Our Future Performance" in the Company's Annual Report on Form 10-K for the year ended December 31, 2004 filed with the Securities and Exchange Commission and those set forth under the heading "Factors That May Affect our~~

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~~Future Performance" in this report. In light of these risks and uncertainties, the forward looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward looking statements.~~

~~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 report.~~

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~~ITEM 3. QUANTITATIVE 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 impact 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 Rate Risk~~

~~A discussion of foreign currency exchange risks is provided under the caption "International Operations" under "Management's Discussion and Analysis of Financial Condition and Results of Operations".~~

~~Interest Rate Risk — Marketable Securities~~

~~We are exposed to the risk of interest rate fluctuations on the fair value and interest income earned on our cash and cash equivalents and investments in available for sale marketable debt securities. A hypothetical 100 basis point movement in interest rates applicable to our cash and cash equivalents and investments in marketable debt securities outstanding at March 31, 2005 would increase or decrease interest income by approximately \$1.6 million on an annual basis. We are not subject to material foreign currency exchange risk with respect to these investments.~~

~~Interest Rate Risk — Long Term Debt and Related Hedging Instruments~~

~~We are exposed to the risk of interest rate fluctuations on the net interest received or paid under the terms of an interest rate swap. At March 31, 2005, we had outstanding a \$50.0 million notional amount interest rate swap used to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of our \$120.0 million principal amount fixed rate 2 1/2% contingent convertible subordinated notes due March 2008.~~

~~Our interest rate swap agreement qualifies as a fair value hedge under SFAS No. 133, as amended, "Accounting for Derivative Instruments and Hedging Activities". At March 31, 2005, the net fair value of the interest rate swap approximated \$2.1 million and is included in other liabilities. The net fair value of the interest rate swap represents the estimated receipts or payments that would be made to terminate the agreement. A hypothetical 100 basis point movement in interest rates applicable to the interest rate swap would increase or decrease interest expense by approximately \$500,000 on an annual basis.~~

~~ITEM 4. CONTROLS AND PROCEDURES~~

~~Evaluation of Disclosure Controls and Procedures~~

~~We maintain disclosure controls and procedures that are designed to ensure 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 for 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 Rule 13a-15(b) under the Exchange Act, 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 the end of the quarter covered by this report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.~~

~~Changes in Internal Control Over Financial Reporting~~

~~No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2005, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.~~

~~Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.~~

~~PART II. OTHER INFORMATION~~

~~ITEM 1. LEGAL PROCEEDINGS~~

~~In July 1996, the Company filed a patent infringement lawsuit in the United States District Court for the Southern District of California (the "Trial Court") against Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps, seeking damages and injunctive relief. The complaint charged, among other things, that the defendant Merck KGaA willfully and deliberately induced, and continues willfully and deliberately to induce, defendants Scripps Research Institute and Dr. Cheresh to infringe certain of the Company's patents. These patents are part of a group of patents granted to The Burnham Institute and licensed by Integra that are based on the interaction between a family of cell surface proteins called integrins and the arginine glycine aspartic acid ("RGD") peptide sequence found in many extracellular matrix proteins. The defendants filed a countersuit asking for an award of defendants' reasonable attorney fees.~~

~~In March 2000, a jury returned a unanimous verdict in the Company's favor and awarded Integra \$15.0 million in damages, finding that Merck KGaA had willfully infringed and induced the infringement of our patents. The Trial Court dismissed Scripps and Dr. Cheresh from the case.~~

~~In October 2000, the Trial Court entered judgment in Integra's favor and against Merck KGaA in the case. In entering the judgment, the Trial Court also granted to the Company pre judgment interest of \$1.4 million, bringing the total award to \$16.4 million, plus post judgment interest. Merck KGaA filed various post trial motions requesting a judgment as a matter of law notwithstanding the verdict or a new trial, in each case regarding infringement, invalidity and damages. In September 2001, the Trial Court entered orders in favor of Integra and against Merck KGaA on the final post judgment motions in the case, and denied Merck KGaA's motions for judgment as a matter of law and for a new trial.~~

~~Merck KGaA and Integra each appealed various decisions of the Trial Court to the United States Court of Appeals for the Federal Circuit (the "Circuit Court"). In June 2003, the Circuit Court affirmed the Trial Court's finding that Merck KGaA had infringed our patents. The Circuit Court also held that the basis of the jury's calculation of damages was not clear from the trial record, and remanded the case to the Trial Court for further factual development and a new calculation of damages consistent with the Circuit Court's decision. Merck KGaA filed a petition for a writ of certiorari with the United States Supreme Court (the "Supreme Court") seeking review of the Circuit Court's decision, and the Supreme Court granted the writ in January 2005. Oral arguments before the United States Supreme Court were held in April 2005. We expect the Supreme Court to render a decision before the end of its current term.~~

~~In September 2004, the Trial Court ordered Merck KgaA to pay Integra \$6.4 million in damages, following the Circuit Court's order. Further enforcement of the Trial Court's order has been stayed pending the decision of the Supreme Court.~~

~~The Company has not recorded any gain in connection with this matter, pending final resolution and completion of the appeals process.~~

~~In addition to the Merck KGaA matter, 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 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 the~~

~~Company's 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.~~

~~Three of the Company's French subsidiaries that were acquired from the neurosciences division of NMT Medical, Inc. received a tax reassessment notice from the French tax authorities seeking in excess of 1.7 million euros in back taxes, interest and penalties. NMT Medical, the former owner of these entities, has agreed to indemnify Integra against direct damages and liability arising from misrepresentations in connection with these tax claims. In April 2005, NMT Medical, Inc. negotiated a settlement agreement with the French authorities that will satisfy the outstanding tax assessments. This settlement will not have any impact on the Company's financial statements.~~

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~~

~~32.1 Certification of Principal Financial Officer Pursuant to Section 906 of
the Sarbanes Oxley Act of 2002.~~

~~_____~~ 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: May 10, 2005 _____ /s/ Stuart M. Essig~~

~~_____ Stuart M. Essig
_____ President and Chief Executive Officer~~

~~_____ Date: May 10, 2005 _____ /s/ David B. Holtz~~

~~_____ David B. Holtz
_____ Senior Vice President, Finance~~

Exhibits

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~~32.2 Certification of Principal Financial Officer Pursuant to Section 906 of
the Sarbanes Oxley Act of 2002.~~

~~I, Stuart M. Essig, certify that:~~

- ~~1. I have reviewed this quarterly report on Form 10-Q of Integra LifeSciences Holdings Corporation;~~
- ~~2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;~~
- ~~3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;~~
- ~~4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - ~~(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;~~
 - ~~(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;~~
 - ~~(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and~~
 - ~~(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and~~~~
- ~~5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - ~~(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and~~
 - ~~(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.~~~~

~~/s/ Stuart M. Essig~~

~~Stuart M. Essig~~

~~President and Chief Executive Officer~~

~~I, David B. Holtz, certify that:~~

- ~~1. I have reviewed this quarterly report on Form 10-Q of Integra LifeSciences Holdings Corporation;~~
- ~~2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;~~
- ~~3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;~~
- ~~4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - ~~(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;~~
 - ~~(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;~~
 - ~~(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and~~
 - ~~(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and~~~~
- ~~5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - ~~(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and~~
 - ~~(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.~~~~

~~Date: May 10, 2005~~

~~/s/ David B. Holtz~~

~~David B. Holtz~~

~~Senior Vice President, Finance~~

~~I, Stuart M. Essig, Chief Executive Officer and Director of Integra LifeSciences Holdings Corporation (the "Company"), hereby certify that, to my knowledge:~~

- ~~1. The Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2005 (the "Report") fully complies with the requirement of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and~~
- ~~2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.~~

~~Date: May 10, 2005 _____ /s/ Stuart M. Essig~~

~~_____ Stuart M. Essig
_____ President and Chief Executive Officer~~

~~I, David B. Holtz, Senior Vice President, Finance and Treasurer of Integra LifeSciences Holdings Corporation (the "Company"), hereby certify that, to my knowledge:~~

- ~~1. The Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2005 (the "Report") fully complies with the requirement of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and~~
- ~~2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.~~

~~Date: May 10, 2005~~ _____ /s/ David B. Holtz

_____ David B. Holtz
_____ Senior Vice President, Finance