SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004

COMMISSION FILE NUMBER 0-26224

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

DELAWARE	51-0317849
(STATE OR OTHER JURISDICTION OF	(I.R.S. EMPLOYER
INCORPORATION OR ORGANIZATION)	IDENTIFICATION NO.)

311 ENTERPRISE DRIVE PLAINSBORO, NEW JERSEY 08536 (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

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

INDICATE BY CHECK MARK WHETHER THE REGISTRANT: (1) HAS FILED ALL REPORTS REQUIRED TO BE FILED BY SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 DURING THE PRECEDING 12 MONTHS (OR FOR SUCH SHORTER PERIOD THAT THE REGISTRANT WAS REQUIRED TO FILE SUCH REPORTS), AND (2) HAS BEEN SUBJECT TO SUCH FILING REQUIREMENTS FOR THE PAST 90 DAYS.

/X/ - YES / / - NO

INDICATE BY CHECK MARK WHETHER THE REGISTRANT IS AN ACCELERATED FILER /X/ YES / / NO

AS OF AUGUST 4, 2004 THE REGISTRANT HAD OUTSTANDING 28,768,934 SHARES OF COMMON STOCK, \$.01 PAR VALUE.

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#### PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

(In thousands, except per share amounts)

INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

Three Months Ended June 30, Six Months Ended June 30, ------------- 2004 2003 2004 2003 ---- ----**REVENUES Product revenues** .....\$56,436 \$41,237 \$107,872 \$76,367 Other revenue 1,013 3,149 ----- ------ ----- Total revenues ..... 56,441 42,736 108,885 79,516 COSTS AND EXPENSES Cost of product revenues ..... 21,665 17,090 41,666 30,793 Research and development ..... 2,639 2,777 5,462 5,427 Selling and marketing 24,311 16,658 General and administrative ..... 6,328 4,736 12,185 9,570 Amortization ..... 1,049 762 1,932 1,339 ------- ---- ----- Total costs and expenses ..... 44,841 34,447 85,556 63,787 Operating income 8,289 23,329 15,729 Interest income ..... 983 826 1,911 1,609 Interest expense ..... (823) (1,024) (1,694) (1,031) Other income (expense), net ..... 135 451 118 800 ------ ----- ----- ------Income before income taxes ..... 11,895 8,542 23,664 17,107 Income tax expense ..... 4,377 3,124 8,708 6,251 ----- ------ ---- Net income..... \$ 7,518 \$ 5,418 \$14,956 \$10,856 ====== ====== ====== ===== Basic net income per share ..... \$ 0.25 \$ 0.19 \$ 0.50 \$ 0.37 Diluted net income per share ..... \$ 0.24 \$ 0.18 \$ 0.48 \$ 0.36 Weighted average common shares outstanding: Basic ..... 29,854 28,484 29,779 28,961 Diluted 30,061 30,911 30,463 The accompanying notes are an integral part of these consolidated financial statements



# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED BALANCE SHEETS (UNAUDITED) In thousands, except per share amounts

In thousands, except per share amounts		
	June 30, 2004	December 31, 2003
ASSETS Current Assets: Cash and cash equivalents \$ 42,540 \$ 78,979 Short-		
term investments		
25,841 29,567 Accounts receivable, net of allowances of		
<del>\$2,193 and \$2,025 35,651 28,936 Inventories</del>		
41,046 Prepaid expenses and other current assets		
current assets		
187,893 Non-current investments		
125,855 98,197		
Property, plant, and equipment, net		
22,540 20,072 Deferred income		
taxes, net		
Identifiable intangible assets, net		
Goodwill		
5,504 5,877		
Total assets		
<del>\$ 435,400</del>		
<pre>\$ 412,526 ====== ======= LIABILITIES AND</pre>		
STOCKHOLDERS' EQUITY Current Liabilities: Accounts		
payable, trade 6,630		
7,947 Income taxes payable		
expenses and other current liabilities 15,177 11,897 Total current liabilities		
23,184 20,618 Long-term debt		
<del>119,257 Other liabilities</del>		
5,608 4,121		
Total liabilities		
····· 147,128 143,996		
Commitments and contingencies		
Stockholders' Equity: Common stock; \$0.01 par		
value; 60,000 authorized shares; 28,970 and 28,611		
issued at June 30, 2004 and December 31, 2003,		
respectively 290 286 Additional paid-in capital		
Treasury stock, at cost; 219 shares at June 30,		
2004 and December 31, 2003 (5,236) (5,236) Other		
(2) (5) Accumulated other comprehensive income		
(loss): Unrealized gains (losses) on available-		
for-sale Securities, net of tax		
currency translation adjustment		
4,976 5,400 Minimum pension liability adjustment,		
net of tax (792) (1,232) Accumulated deficit		
(17,462) Total stockholders'		
equity 288,272		
268,530 Total liabilities and		
stockholders' equity \$ 435,400 \$		
412,526 ======= ======== The accompanying notes		
are an integral part of these consolidated		
financial statements		

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

(In thousands) Six Months Ended June 30, ----------- 2004 2003 ---- OPERATING ACTIVITIES: Net income \$ 14,956 \$ 10,856 Adjustments to reconcile net income to net cash provided by operating activities: Depreciation and intangible asset amortization ..... 4,032 3,223 Deferred income tax provision ..... 6,750 5,027 Amortization of discount and premium on investments ..... 1,203 756 Other, net 391 (42) Changes in assets and liabilities, net of business acquisitions: Accounts receivable (749) Inventories (5,976) (1,555) Prepaid expenses and other current assets ..... (780) 968 Non-current assets ..... (24) 558 Accounts payable, accrued expenses and other liabilities ..... 3,320 4,046 ----- Net cash provided by operating activities ..... 20,875 23,088 -------- INVESTING ACTIVITIES: Proceeds from sales/maturities of available-for-sale investments. 73,438 79,652 Purchases of available-for-sale investments ..... (100,531) (74,569) Cash used in business acquisition, net of cash acquired ..... (28,953) (42,155) Purchases of property and equipment ..... (4,813) (1,449) ------ Net cash used in investing activities ..... (60,859) (38,521) ----- FINANCING ACTIVITIES: Proceeds from exercised stock options and warrants ...... 3,502 7,076 Purchase of treasury stock ..... -- (35,325) Proceeds from issuance of convertible notes, net ..... -- 116,054 --------- Net cash provided by financing activities ..... 3,502 87,805 ----- ----- Effect of exchange rate changes on cash ..... 43 198 Net increase (decrease) in cash and cash equivalents ..... (36,439) 72,570 Cash and cash equivalents at beginning of period ..... 78,979 43,583 ------- cash and cash equivalents at end of period .....\$ 42,540 \$116,153 ======= ====== 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 June 30, 2004 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, 2003 included in the Company's Annual Report on Form 10-K. Operating results for the three and six month periods ended June 30, 2004 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.

# Recently Issued Accounting Standards

In March 2004, the FASB Emerging Issues 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 recognition and measurement provisions of Issue 03-01 are to be applied to other-than-temporary impairment evaluations in reporting periods beginning after June 15, 2004. The Company does not expect the adoption of Issue 03-01 to have a material impact on its financial position, cash flows or results of operations.

In March 2004, the EITF reached a consensus on Issue 03-6, "Participating Securities and the Two-Class Method Under FASB Statement No. 128". Issue 03-6 expanded the notion of participation rights in calculating earnings per share from previous practice. Issue 03-6 does not focus on a security holder's contractual rights to ultimately receive the undistributed earnings and net assets of the company upon redemption or liquidation. Instead, it defines participation rights based solely on whether the holder would be entitled to receive any dividends declared during the period, even if the company would not declare any dividends during the period due to economic or practical concerns or legal or contractual limitations on the company's ability to pay dividends.

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Under Issue 03-6, all securities that meet the definition of a participating security, regardless of whether the securities are convertible, non-convertible, or potential common stock securities, will be considered for inclusion in the computation of basic earnings per share using the two-class method. The application of the two-class method may also have an impact on the diluted earnings per share calculation due to the need to consider each type of potential common shares in the proper sequence to arrive at maximum dilution.

Integra adopted the provisions of Issue 03-6 during the second quarter ended June 30, 2004. The transition provisions of Issue 03-6 require prior period earnings per share amounts to be restated to conform to the new standard, including the impact relating to securities that have been extinguished but were outstanding for a portion of some prior period that is presented for comparative purposes. Accordingly, in the future, Integra will restate its earnings per share calculations for the year ended December 31, 2001 to conform to the two-class method required by Issue 03-6 as it relates to the dividend participation rights included in the Series B and Series C Convertible Preferred Stock that were outstanding during that period. The adoption of Issue 03-6 will reduce previously reported basic earnings per share by \$0.05 to \$1.03 and diluted earnings per share by \$0.02 to \$0.92 in 2001. The adoption of Issue 03-6 will not change the previously reported basic or diluted earnings per share for any other year.

#### 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".

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 June 30, Six Months Ended June 30, 2004 2003 2004 2003 ------ (in thousands, except per shareamounts) Net income: As reported

<del>\$ 0.25 \$ 0.19 \$ 0.50 \$ 0.37 Pro forma</del>

\$ 0.20 \$ 0.14 \$ 0.40 \$ 0.28
Diluted: As reported

\$ 0.24 \$ 0.18 \$ 0.48 \$ 0.36 Pro forma

\$ 0.20 \$ 0.14 \$ 0.39 \$ 0.27

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 was calculated based on the fair value of each option grant using the Black-Scholes model.

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On March 31, 2004, the FASB issued an Exposure Draft "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95." The Exposure Draft addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally would require instead that such transactions be accounted for using a fair-value based method. The Exposure Draft proposes that the cost of all forms of equity-based compensation granted to employees, excluding employee stock ownership plans, be recognized in a company's income statement and that such cost be measured at the fair value of the stock options. As proposed, the new rules would be applied on a modified prospective basis as defined in the Exposure Draft, and would be effective for fiscal years beginning after December 15, 2004. The Company is currently evaluating option valuation methodologies and assumptions in light of the evolving accounting standards

related to employee stock options. Current estimates of option values using the Black-Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

#### 2. BUSINESS ACQUISITIONS

In May 2004, the Company acquired the MAYFIELD(R) Cranial Stabilization and Positioning Systems and the BUDDE(R) Halo Retractor System business from Schaerer Mayfield USA, Inc. (formerly Ohio Medical Instrument Company) for \$20.0 million in cash paid at closing and a \$0.3 million working capital adjustment. 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 through distributors in international markets.

The acquired business includes a facility located in Cincinnati, Ohio that manufactures, packages and distributes MAYFIELD and BUDDE stabilization products, as well as a broad line of related instruments and disposables used in many neurosurgical and spinal procedures. In addition, as part of the acquisition, Integra entered into a long-term license with SM USA, Inc., a wholly owned subsidiary of Schaerer Mayfield USA, Inc., for the use of the MAYFIELD name in connection with the acquired business.

In connection with this acquisition, the Company preliminarily recorded \$8.2 million of goodwill and \$8.0 million of intangible assets, consisting of a non-compete agreement, trade name, and technology, which are being amortized on a straight-line basis over lives ranging from 5 to 30 years. The following table summarizes the preliminary fair value of the assets acquired and liabilities assumed in this acquisition (in thousands):

<del>Current assets</del>
<del>\$</del>
<del>3,489 Property, plant and</del>
<del>equipment 1,400</del>
<del>Intangible assets</del>
<del>8,030</del>
Goodwill
OOOUWIII
<del></del>
8,191 Total assets
acquired
<del>21,110 Current liabilities</del>
,
<del>768 Net</del>
<del>assets acquired</del>
<del>\$ 20,342</del>

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, subject to a working capital adjustment. 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.

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The acquired business includes a facility located in Tuttlingen, Germany that manufactures, packages and distributes the ELEKTROTOM and SONOTOM products. This acquisition provided Integra with additional devices for the European and international markets and an existing infrastructure through which it can sell certain of its other products directly into Germany.

In connection with this acquisition, the Company preliminarily recorded \$1.8 million of goodwill and \$1.3 million of intangible assets, consisting primarily of trade name, technology, and customer relationships, which are being amortized on a straight-line basis over lives ranging from 3 to 10 years.

In January 2004, the Company acquired the R&B instrument business from R&B Surgical Solutions, LLC for approximately \$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 connection with this acquisition, the Company recorded approximately \$1.5 million of intangible assets and goodwill. The acquired intangible assets are being amortized on a straight-line basis over lives ranging from 5 to 20 years. If the Company had consummated this acquisition as of the beginning of 2003, its operating results would not have been materially different from those herein. In January 2004, the Company acquired the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. for approximately \$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. In connection with this acquisition, the Company recorded approximately \$1.5 million of intangible assets and goodwill. The acquired intangible assets are being amortized on a straight-line basis over 5 years. If the Company had consummated this acquisition as of the beginning of 2003, its operating results would not have been materially different from those herein.

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

In November 2003, the Company acquired all of the outstanding capital stock of Spinal Specialties, Inc. for \$6.4 million in cash. Spinal Specialties markets its products primarily to anesthesiologists and interventional radiologists through an in-house telemarketing team and a network of distributors.

In August 2003, the Company acquired substantially all of the assets of Tissue Technologies, Inc. The Company paid \$0.6 million in cash and is obligated to pay the seller up to an additional \$1.5 million in contingent consideration based upon a multiple of the Company's sales of the UltraSoft(TM) product in the third year following the acquisition. If the Company had consummated this acquisition as of the beginning of 2003, its operating results would not have been materially different from those herein.

In March 2003, the Company acquired all of the outstanding capital stock of J. Jamner Surgical Instruments, Inc. (doing business as JARIT(R) Surgical Instruments) ("JARIT") for \$43.5 million in cash. In the United States, JARIT sells through a twenty-person sales management force that works with over 100 distributor sales representatives.

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The results of operations of acquired businesses are included in the consolidated financial statements since the respective dates of acquisition.

The following unaudited pro forma financial information assumes that the Mayfield, Integra ME, Spinal Specialties and JARIT acquisitions had occurred as of the beginning of 2003 (in thousands, except per share data): For the Six Months Ended June 30, 2004

2003 ----- Total revenue

#### 3. INVENTORIES

Inventories consisted of the following: June 30, December 31, 2004 2003 ---- ---- (in thousands) Raw materials....

4. GOODWILL AND OTHER INTANGIBLE ASSETS

Changes in the carrying amount of goodwill for the six months ended June 30, 2004, were as follows:

Balance at December 31, 2003

R&B acquisition

413 Sparta acquisition

1,037 Mayfield acquisition

8,191 Integra ME acquisition

	-currency translation	<del>-1,844</del>			
<del></del>		<del>. \$</del>			
Bal	ance at June 30, 2004	<del>. \$</del>	assets v	were as	follows:
(265) All other 11 years 2,233 (1,071) 2,909 (854)					
<pre>\$ 70,985 \$ (9,393)     \$ 59,961 \$     (7,526)     Accumulated amortization (9,393) (7,526) -</pre>					
\$ 61,592 \$ 52,435					

Annual amortization expense is expected to approximate \$4.3 million in 2004, \$4.6 million in 2005, \$4.6 million in 2006, \$4.3 million in 2007, and \$3.7 million in 2008. Identifiable intangible assets are initially recorded at fair market value at the time of acquisition generally using an income or cost approach.

gains (losses) on available-for-sale securities: Unrealized holding loss during the period, net of tax ..... (1,578) (78) (1,255) (217) Less: reclassification adjustment for gains included in net income -----Comprehensive income .....\$ 5,703 \$ 6,719 \$ 13,717 \$ 11,667 ====== 6. NET INCOME PER SHARE Basic and diluted net income per share were as follows: Three Months Ended Six Months Ended June 30, June 30, ---------- 2004 2003 2004 2003 ----- (In thousands, except (In thousands, except per share amounts) per share amounts) Basic net income per share: - ----------- Net income available to common stock ..... \$ 7,518 \$ 5,418 \$14,956 \$10,856 Weighted average common shares outstanding ..... 29,854 28,484 29,779 28,961 Basic net income per share ..... \$ 0.25 \$ 0.19 \$ 0.50 \$ 0.37 Diluted net income per share: - ---- Net income available to common stock .....\$ 7,518 \$ 5,418 \$14,956 \$10,856 Weighted average common shares outstanding - Basic ... 29,854 28,484 29,779 28,961 Effect of dilutive securities - stock options and warrants 1,110 1,577 1,132 1,502 ----------- Weighted average common shares outstanding for diluted earnings per share ..... 30,964 30,061 30,911 30,463 Diluted net income per share ..... \$ 0.24 \$ 0.18 \$ 0.48 \$ 0.36

Options and warrants outstanding at June 30, 2004 and 2003, respectively, to purchase 29,000 and 659,000 shares of common stock were excluded from the computation of diluted net income per share for the three and six month periods ended June 30, 2004 and 2003 because their exercise price exceeded the average market price of the Company's common stock during the period.

Notes payable outstanding at June 30, 2004 and 2003 that were convertible into 3.5 million shares of common stock were excluded from the computation of diluted net income per share for the three and six month periods ended June 30, 2004 and

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2003, respectively, because the conditions required to convert the notes were not met. Holders have the right to convert their notes into shares of the Company's common stock at any time prior to their maturity, if any of the following conditions is met:

- the last sale price of the Company's common stock on the trading day prior to the conversion date was 110% or more of the conversion price on such trading day;
- the Company distributes to holders of its common stock certain rights entitling them to purchase common stock at less than the last sale price of our common stock on the day preceding the declaration for such distribution;
- the Company distributes to holders of its common stock assets, debt, securities or certain rights to purchase its securities, which distribution has a per share value exceeding 10% of the last sale price of the Company's common stock on the day preceding the declaration of such distribution; or
  - the Company becomes a party to a consolidation, merger or sale of all or substantially all of its assets or a change in control occurs pursuant to which the Company's common stock would be converted into cash, stock or other property that is not common equity interests

traded on a national securities exchange or quoted on the Nasdaq National Market;

Holders may also convert their notes into shares of the Company's common stock as follows:

- at any time prior to March 15, 2006 after any 5 consecutive trading-day period in which the average trading prices for the notes for that 5 trading-day period was less than 103% of the average conversion value for the notes during that period; or
  - at any time on or after March 15, 2006 and prior to maturity after any 5 consecutive trading-day period in which the average trading prices for the notes for that 5 trading-day period was less than 97% of the average conversion value for the notes during that period (however, holders may not convert their notes on or after March 15, 2006 if, at the time of the calculation, the closing sale price of shares of the Company's common stock is between the then current conversion price on the notes and 110% of the then current conversion price on the notes.)

# 7. PRODUCT REVENUE AND GEOGRAPHIC INFORMATION

Integra develops, manufactures, and markets medical devices for use primarily in neuro-trauma and neurosurgery, plastic and reconstructive surgery, and general surgery. The Company's product lines include monitoring and drainage systems, surgical instruments, fixation systems, and innovative tissue repair products that incorporate the Company's proprietary absorbable implant technology. The Company reports its financial results under a single operating segment - the development, manufacturing, and distribution of medical devices.

Product revenues are segregated into the following categories: Three Months Ended Six Months Ended

June 30, June 30,
2004 2003 2004 2003
(in
thousands) <del>Neuromonitoring</del>
products\$
<del>11,813 \$ 10,552 \$ 23,011 \$ 21,084</del>
Operating room
<del>products</del>
<del>19,412 12,833 37,744 25,421 Instruments</del>
<del></del>
<del>19,006 12,358 35,049 18,605 Private</del>
label products
<del></del>
5,494 12,068 11,257
-, - , - , -
Total product revenues
<del>\$ 56,436</del>
<del>\$ 41,237 \$107,872 \$ 76,367</del>

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Beginning in 2004, the Company has included the sales of INTEGRA(R) Dermal Regeneration Template in operating room product revenues. In the prior year period, these product sales were included in private label product revenues.

Certain of the Company's products, including the DuraGen(R) Dural Graft products, NeuraGen(TM) Nerve Guide, INTEGRA(R) Dermal Regeneration Template, INTEGRA(TM) Bilayer 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 approximately 32% and 29% of product revenues in the six month periods ended June 30, 2004 and June 30, 2003, 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.

Product revenues by major geographic area are summarized below: United Asia Other States Europe Pacific Foreign Total ----

-- -----

(in thousands) Product revenues: Three months ended June 30, 2004 ... \$ 44,979 \$ 7,561 \$ 2,069 \$ 1,827 \$ 56,436 Three months ended June 30, 2003 ... 33,105 5,721 1,186 1,225 41,237 Six months ended June 30, 2004 ....\$ 85,366 \$ 14,809 \$ 3,898 \$ 3,799 \$107,872 Six months ended June 30, 2003 . . . . . 60,367 10,722 2,644 2,634 76,367

# 8. COMMITMENTS AND CONTINGENCIES

As consideration for certain technology, manufacturing, distribution and selling rights and licenses granted to Integra, the Company has agreed to pay royalties on the sales of products that use the granted rights and licenses. Royalty payments under these agreements by the Company were not significant for any of the periods presented.

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, Integra 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 Integra's patents. The Trial Court dismissed Scripps and Dr. Cheresh from the case.

to the Company pre-judgment interest of approximately \$1.4 million, bringing the total award to approximately \$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 the Company 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 Integra's 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.

The Trial Court has scheduled oral argument on damages on August 27, 2004. Integra has not recorded any gain in connection with this matter.

Three of the French subsidiaries that the Company 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, Inc., the former owner of these entities, has agreed to specifically indemnify Integra against any liability in connection with these tax claims. In addition, NMT Medical, Inc. has agreed to provide the French tax authorities with payment of the tax liabilities on behalf of each of these subsidiaries.

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

#### 9. SUBSEQUENT EVENT

In July 2004, Stuart M. Essig, the Company's President and Chief Executive Officer, renewed his employment agreement with the Company through December 31, 2009. In connection with the renewal of the agreement, Mr. Essig received a grant of fair market value options to acquire up to 250,000 shares of Integra common stock and a fully vested contract stock unit award providing for the payment of 750,000 shares of Integra common stock which shall generally be delivered to Mr. Essig upon a change of control, following his termination of employment or retirement after December 31, 2009, or later under certain circumstances. The Company expects to record an after-tax non-cash compensation charge of approximately \$14.9 million in the third quarter of 2004 for the deferred payment related to the fully-vested contract stock unit grant.

# 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, 2003 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 primarily in neuro-trauma, neurosurgery, plastic and reconstructive surgery, and general surgery. Our product lines include monitoring and drainage systems, surgical instruments, fixation systems and innovative tissue repair products that incorporate our proprietary absorbable implant technology.

Our business is organized into product groups and distribution channels. Our product groups include implants and other devices for use in the operating room, 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 a sales organization that we employ to call on neurosurgeons, another employed sales force to call on plastic and reconstructive surgeons, and networks of third-party distributors that we manage. 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 manufacture most of the operating room, 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 that we sell, but we purchase most of our hand-held surgical instruments from 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 32% and 29% of product revenues in the six months ended June 30, 2004 and June 30, 2003, 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 product lines.

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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 from products internally developed or acquired products, 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 increase from the level we reported in 2003, and earnings per fully diluted share of common stock.

#### ACQUISITIONS

Our strategy for growing our business includes the acquisition of complementary product lines, technologies, and companies. Recent acquisitions (as discussed in Note 2 to our unaudited consolidated financial statements), may make our financial results for the three and six month periods ended June 30, 2004 not directly comparable to those of the corresponding prior year period.

RESULTS OF OPERATIONS

Our revenues for the periods were as follows: Three Months Ended Six Months Ended June 30, June 30, ------(in thousands) 2004 2003 2004 2003 ----- ------ Total Neuromonitoring product revenues ..... \$11,813 \$10,552 \$23,011 \$21,084 Total Operating Room product revenues ..... 19,412 12,833 37,744 25,421 Total Instruments product revenues ..... 19,006 12,358 35,049 18,605 Total Private Label product revenues ..... 6,205 5,494 12,068 11,257 ----- ------- ---- Total product revenues ..... \$56,436 \$41,237 \$107,872 \$76,367 Other revenue 5 1,499 1,013 3,149 ------- ----- Total revenues \$56,441 \$42,736 \$108,885 \$79,516

QUARTER ENDED JUNE 30, 2004 COMPARED TO QUARTER ENDED JUNE 30, 2003

Total Revenues And Gross Margin On Product Revenues:

For the quarter ended June 30, 2004, total revenues were \$56.4 million, an increase of \$13.7 million, or 32%, over the quarter ended June 30, 2003. This increase was primarily attributable to an increase in product revenues of \$15.2 million, or 37%, over the prior-year period. Other revenue decreased by \$1.5 million primarily due to the termination of the ETHICON distribution and development agreement in December 2003. The increase in product revenues generated by our selling the INTEGRA(R) Dermal Regeneration product directly to end customers has more than offset this decrease.

Revenues from product lines acquired since the second quarter of 2003 accounted for \$4.2 million of the \$13.7 million increase in total revenues over the prior year period. Changes in foreign currency exchange rates contributed \$515,000 to the increase in total revenues. Domestic product revenues increased \$11.9 million in the second quarter of 2004 to \$45.0 million, or 80% of product revenues, the same percentage reported for the second quarter ended June 30, 2003.

Revenues from our monitoring product lines increased \$1.3 million, or 12%, over the prior-year period, primarily as a result of increased sales of our intracranial monitoring products and drainage systems. Our operating room product line revenues increased over the prior-year period by \$6.6 million, or 51%. This increase is largely the result of growth in sales of our DuraGen(R)

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and DuraGen Plus(TM) Dural Graft Matrix products and the inclusion of INTEGRA(R) Dermal Regeneration Template sales in the operating room category. Prior to resuming the direct sale and marketing of the INTEGRA product on January 1, 2004, we reported sales of the INTEGRA product to ETHICON, Inc. in the private label category.

Revenues from our instrument product lines increased by \$6.6 million, or 54%, over the prior-year period and included \$4.2 million of revenues from product lines acquired since the second quarter of 2003. The remaining \$2.4 million increase was led by growth in the JARIT surgical instrument line. We also experienced growth over the prior year period in each of our existing instrument product lines. Our private label product revenue increased by \$711,000, or 13%, over the prior year period as increased revenues from the Absorbable Collagen Sponge we supply for use in Medtronic's INFUSE bone graft product offset the removal of INTEGRA Dermal Regeneration Template revenues from this category. Although sales of certain private label products vary highly from quarter to quarter depending on the timing and size of orders placed by our marketing partners, we do not believe that the variability is as significant on an annual basis.

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

Our gross margin on product revenues was 62% in the quarter ended June 30, 2004, as compared to 59% in the prior-year period. The current quarter's gross margin benefited from strong sales growth of our higher margin products during the quarter, the resumption of direct sales of INTEGRA Dermal Regeneration Template, and the decrease in fair value purchase accounting adjustments for acquired inventory. Our reported gross margins for the second quarter of 2004 and 2003 included \$70,000 and \$514,000, respectively, of fair value purchase accounting adjustments for acquired inventory sold during the quarter.

Other Operating Expenses:

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

Three Months Ended June 30, (in thousands) 2004 2003 -----

- Research and development

 % 7 % Selling and marketing

 23 % 22 % General and

 administrative

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<del>% 11 %</del>

Total other operating expenses, which exclude cost of product revenue but include amortization, increased 34% to \$23.2 million in the second quarter of 2004, compared to \$17.4 million in the second quarter of 2003.

Research and development expenses decreased \$138,000 to \$2.6 million in the second quarter of 2004. Increased clinical studies and new product development activities in neurosurgical and plastic and reconstructive applications largely offset the savings that resulted from the closing of our San Diego research center in the fourth quarter of 2003.

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The continuing decline in research and development expenses as a percentage of product revenues in recent quarters is partially related to the significant increase in hand-held instrument product revenues as a proportion of our total revenues. By their nature, our hand-held instrument product lines require less research and development and depend more on sales and marketing efforts to support growth.

We are obligated to pay \$1.5 million to the sellers of the Novus Monitoring Limited assets upon their achievement of a product development milestone. If such payment is made, we estimate that approximately \$1.0 million will be recorded as an in-process research and development charge.

Sales and marketing expenses increased 45% over the prior-year period to \$13.2 million as a result of the continued expansion of our domestic direct sales and marketing organizations, increased spending to support our plastic and reconstructive surgery product lines, and the recently acquired MAYFIELD, BUDDE, ELEKTROTOM and SONOTOM product lines. Sales and marketing expenses were 23% and 22% of product revenues in the three months ended June 30, 2004 and June 30, 2003, respectively.

General and administrative expenses increased \$1.6 million to \$6.3 million in the second quarter of 2004, largely as a result of increased professional fees related to Sarbanes-Oxley internal control initiatives, the implementation of our new global enterprise resource management system, and our litigation with Merck KGaA. General and administrative expenses were 11% of product revenues in the three months ended June 30, 2004 and June 30, 2003. We expect general and administrative expenses as a percentage of product revenues to remain consistent with these levels through the remainder of 2004 and into 2005.

Amortization expense increased \$287,000 to \$1.0 million in the second quarter of 2004 as a result of amortization of intangible assets from recent acquisitions.

In the second half of 2004, we expect to incur approximately \$1.5 million of operating charges related to the MAYFIELD acquisition, including inventory fair value purchase accounting costs, facilities consolidation expenses, and distributor termination payments, and our planned relocation of our National Distribution Center from Plainsboro, New Jersey to Reno, Nevada in the fourth quarter. Additionally, in July 2004, Stuart M. Essig, our President and Chief Executive Officer, renewed his employment agreement with Integra to extend the term of his employment through December 31, 2009. In connection with the renewal of the agreement, Mr. Essig received a grant of fair market value options to acquire up to 250,000 shares of Integra common stock and a fully vested contract stock unit award providing for the payment of 750,000 shares of Integra common stock which shall generally be delivered to Mr. Essig following his termination of employment or retirement, but not before December 31, 2009, or later under certain circumstances, or upon a change of control. In the third guarter of 2004, we expect to record an after-tax non-cash compensation operating charge of approximately \$14.9 million for the deferred payment related to the fully-vested contract stock unit grant.

# Non-Operating Income And Expenses

In the second quarter of 2004, we recorded \$823,000 in net interest expense associated with the \$120 million of contingent convertible subordinated notes we issued in 2003 and a related interest rate swap agreement. The \$201,000 decrease as compared to the second quarter of 2003 reflects the benefits we received from an interest rate swap executed in August 2003.

Our reported interest expense includes \$205,000 of non-cash amortization of debt issuance costs. Debt issuance costs totaled \$4.1 million and are being amortized using the straight-line method over the five-year term of the notes.

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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 second quarter of 2004 and 2003, the change in the estimated fair value of the Contingent Interest obligation was 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. Included in interest expense for the three months ended June 30, 2004 is a \$216,000 reduction in interest expense associated with the interest rate swap.

The net fair value of the interest rate swap at March 31, 2004 was \$563,000. At June 30, 2004, the net fair value of the interest rate swap increased \$1.4 million to \$2.0 million, and this amount is included in other liabilities. In connection with this fair value hedge transaction, during the second quarter of 2004, we recorded a \$1.4 million net decrease 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 is recorded in other income.

Our net other income/expense decreased by \$316,000 from \$451,000 of income in the second quarter of 2003 to \$135,000 of income in the second quarter of 2004. In the second quarter of 2003, we recorded \$279,000 of gains realized on the sale of marketable securities.

Income tax expense was approximately 36.8% and 36.6% of income before income taxes for the second quarters of 2004 and 2003, respectively. Included in income tax expense for the second quarters of 2004 and 2003 was a deferred income tax provision of \$3.6 million and \$2.4 million, respectively. The increase in the effective income tax rate in 2004 resulted primarily from a change in the geographic mix of projected taxable income for 2004.

For the second quarter of 2004, we reported net income of \$7.5 million, or \$0.24 per diluted share, as compared to net income of \$5.4 million, or \$0.18 diluted

per share, for the prior year quarter.

In periods when the holders of our contingent convertible notes are permitted to exercise their conversion rights, the "if-converted" method will be used to determine the dilutive effect on earnings per share of the notes, which are convertible into approximately 3.5 million shares of common stock.

At its July 1, 2004 meeting, the FASB Emerging Issue Task Force (EITF) reached a tentative consensus on Issue 04-08 that would require 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 would be applied retroactively, with no grandfathering provision for existing contingent convertible securities.

The FASB has published a draft abstract of Issue 04-08 and the EITF will review comments on this proposal at its September 2004 meeting. If the tentative consensus reached in Issue 04-08 is ratified by the FASB, we expect that it would reduce our previously reported diluted earnings per share results by \$0.01 for both the six months ended June 30, 2004 and the year ended December 31, 2003. Issue 04-08 is also expected to have a dilutive effect on our future earnings per share estimates.

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SIX MONTHS ENDED JUNE 30, 2004 COMPARED TO SIX MONTHS ENDED JUNE 30, 2003

For the six months ended June 30, 2004, total revenues increased by \$29.4 million, or 37%, over the six months ended June 30, 2003 to \$108.9 million. Product revenues increased by \$31.5 million, or 41%, over the prior year period. Other revenue decreased by \$2.1 million primarily due to the termination of the ETHICON distribution and development agreement in December 2003.

Revenues from products acquired since the beginning of 2003 accounted for \$14.4 million of the \$29.4 million increase in total revenues over the prior year period. Changes in foreign currency exchange rates contributed \$1.5 million to the increase in total revenues. Domestic product revenues increased \$25.0 million during 2004 to \$85.4 million, or 79% of product revenues, the same percentage reported for the six months ended June 30, 2003.

Revenues from our monitoring product lines increased \$1.9 million, or 9%, over the prior-year period primarily as a result of increased sales of our intracranial monitoring products and drainage systems. Our operating room product line revenues increased over the prior year period by \$12.3 million, or 48%. This increase is largely the result of growth in sales of our DuraGen(R) and DuraGen Plus(TM) Dural Graft Matrix products and the inclusion of INTEGRA(R) Dermal Regeneration Template sales in the operating room category.

Revenues from our instrument product lines increased by \$16.4 million, or 88%, over the prior-year period. This increase resulted from the impact of recently acquired product lines and strong sales growth in each of our existing instrument product lines. Our private label product revenue increased by \$811,000, or 7%, over the prior-year period, as increased revenues from the Absorbable Collagen Sponge we supply for use in Medtronic's INFUSE bone graft product offset the removal of INTEGRA Dermal Regeneration Template revenues from this category.

Our gross margin on product revenues for the six months ended June 30, 2004 was 61%, as compared to 60% for the prior-year period. The benefit of strong growth in sales of our higher margin products, the resumption of direct sales of INTEGRA Dermal Regeneration Template in 2004, and a reduction in fair value purchase accounting adjustments more than offset the impact of the lower margins associated with recently acquired instrument product lines. Our reported gross margins for the six months ended June 30, 2004 and June 30, 2003 included \$70,000 and \$860,000, respectively, of fair value purchase accounting adjustments for acquired inventory sold during the periods.

Other Operating Expenses:

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

Six Months Ended June 30, (in thousands) 2004 2003 ------ Research and development

% 7 % Selling and marketing

<del>% 13 %</del>

Total other operating expenses, which exclude cost of product revenue but include amortization, increased 33% to \$43.9 million in the six months ended June 30, 2004, compared to \$33.0 million in the prior-year period.

Research and development expenses increased \$35,000 to \$5.5 million in the six months ended June 30, 2004. Increased clinical studies and new product development activities in neurosurgical and plastic and reconstructive applications offset the savings that resulted from closing our San Diego research center. Research and development expenses on products other than our traditional hand-held instruments was 7% of product revenues in 2004, as compared to 9% in the prior year period.

Sales and marketing expenses increased 46% over the prior year period to \$24.3 million as a result of the continued expansion of our domestic direct sales and marketing organizations, increased spending to support our plastic and reconstructive surgery product lines, and sales and marketing expenses of recently acquired businesses. Sales and marketing expenses were 23% and 22% of product revenues in the six months ended June 30, 2004 and June 30, 2003, respectively.

General and administrative expenses increased \$2.6 million to \$12.2 million in the six months ended June 30, 2004, largely as a result of increased professional fees related to Sarbanes-Oxley internal control initiatives, the implementation of our new global enterprise resource management system, and our litigation with Merck KGaA.

Amortization expense increased \$593,000 to \$1.9 million in 2004 as a result of amortization of intangible assets from recent acquisitions.

Non-Operating Income and Expenses

We recorded net interest income of \$217,000 in the six months ended June 30, 2004, as compared to net interest income of \$578,000 in the prior-year period. This decrease resulted from the six months of interest expense recorded in 2004 associated with the \$120 million of contingent convertible subordinated notes we issued in March and April of 2003, offset by the benefits we received from the interest rate swap.

Our reported interest expense in 2004 and 2003, respectively, includes \$410,000 and \$215,000 of non-cash amortization of debt issuance costs. The change in the estimated fair value of the Contingent Interest obligation increased interest expense by \$163,000 and \$44,000 in 2004 and 2003, respectively. Included in interest expense for the six months ended June 30, 2004 is a \$426,000 reduction in interest expense associated with the interest rate swap.

The net fair value of the interest rate swap at December 31, 2003 was \$1.1 million. At June 30, 2004, the net fair value of the interest rate swap

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increased \$882,000 to \$2.0 million, and this amount is included in other liabilities. In connection with this fair value hedge transaction, during the six months ended June 30, 2004, we recorded a \$957,000 net decrease 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 (expense), net.

Our net other income/expense decreased by \$682,000 from \$800,000 of income in

2003 to \$118,000 of income in 2004. In 2003, we recorded \$500,000 of gains realized on the sale of marketable securities.

Income tax expense was approximately 36.8% and 36.5% of income before income taxes for 2004 and 2003, respectively. Included in income tax expense in 2004 and 2003 was a deferred income tax provision of \$6.8 million and \$5.0 million, respectively. The increase in the effective income tax rate in 2004 resulted primarily from a change in the geographic mix of projected taxable income for 2004.

For the six months ended June 30, we reported net income of \$15.0 million, or \$0.48 per diluted share, as compared to net income of \$10.9 million, or \$0.36 diluted per share, for the prior year period.

#### International Product Revenues and 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 foreign currency denominated revenues or expenses.

In the six-month period ended June 30, 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. 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.

Product revenues by major geographic area are summarized below: United Asia Other States Europe Pacific Foreign Total ----------- ------- ------ -----(in thousands) Product revenues: Three months ended June 30, 2004 <del>...\$</del> 44,979 \$ 7,561 \$ 2,069 \$ 1,827 \$ 56,436 Three months ended June <del>30, 2003</del> ... 33,105 <del>5,721</del> <del>1,186</del> <del>1,225</del> 41,237 Six months ended June 30, 2004 <del>....\$</del> 85,366 \$ 14,809 \$ 3,898 \$ 3,799 \$107,872 Six months ended June <del>30, 2003</del> <del>. . . . .</del> 60,367 <del>10,722</del> 2,644 2,634 76,367

In the six months ending June 30, 2004, product revenues from customers outside the United States totaled \$22.5 million, or 21% of consolidated product revenues, of which approximately 66% were to European customers. Of this amount, \$16.5 million was generated in foreign currencies.

In the six months ending June 30, 2003, product revenues from customers outside the United States totaled \$16.0 million, or 21% of consolidated product revenue, of which approximately 67% were to European customers. Of this amount, \$8.3 million was generated in foreign currencies by our subsidiaries in Europe.

# LIQUIDITY AND CAPITAL RESOURCES

#### Cash and Marketable Securities

At June 30, 2004, we had cash, cash equivalents and current and non-current investments totaling approximately \$194.3 million. Our investments consist almost entirely of highly liquid, interest bearing debt securities. We believe that our cash and marketable securities are sufficient to finance our operations and capital expenditures in the short term. However, given the significant level of liquid assets and our objective to grow by acquisitions and alliances, our financial position and future financial results could change significantly if we were to use a significant portion of our liquid assets.

#### 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 generated positive operating cash flows of \$32.0 million in 2002, \$34.8 million in 2003, and \$20.9 million in the six months ending June 30, 2004. Operating cash flows for the six months ending June 30, 2003, were \$23.1 million. Operating cash flows for the six months ended June 30, 2004 declined as compared to the prior year because of additional investments in inventory to support our growth in product revenues and higher accounts receivable balances related to increased sales.

Our principal uses of funds during the six month period ended June 30, 2004 were \$28.9 million for acquisition consideration, \$27.1 million for purchases of investments, net of maturities and sales, and \$4.8 million for purchases of property and equipment. In 2004, we have increased cash outlays for capital expenditures as compared to 2003, primarily because of an estimated \$4 million of expenditures associated with planned information system upgrades. In addition to the \$20.9 million in operating cash flows, we received \$3.5 million from the issuance of common stock through the exercise of stock options during the period.

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#### Working Capital

At June 30, 2004 and December 31, 2003, working capital was \$141.0 million and \$167.3 million, respectively. The decrease in working capital was primarily due to cash invested in marketable debt securities during the period, offset by additional investments in inventory to support our growth in product revenues and higher accounts receivable balances related to increased sales.

Convertible Debt and Related Hedging Activities

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.

#### Share Repurchase Plans

In March 2004, our Board of Directors authorized us to repurchase up to 1.5 million shares of our common stock for an aggregate purchase price not to exceed \$40.0 million. We may repurchase shares under this program through March 2005 either in the open market or in privately negotiated transactions. We did not repurchase any shares of common stock during the first six months of 2004 under this program or under the previous program which expired in February 2004.

# **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. In 2004, we have increased cash outlays for capital expenditures as compared to 2003, primarily because of an estimated \$4 million of expenditures associated with planned information system upgrades.

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.

#### RECENTLY ISSUED ACCOUNTING STANDARDS

In March 2004, the FASB Emerging Issues 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 recognition and measurement provisions of Issue 03-01 are to be applied to other-than-temporary impairment evaluations in reporting periods beginning after June 15, 2004. The Company does not expect the adoption of Issue 03-01 to have a material impact on its financial position, cash flows or results of operations.

In March 2004, the EITF reached a consensus on Issue 03-6, "Participating Securities and the Two-Class Method Under FASB Statement No. 128". Issue 03-6 expanded the notion of participation rights in calculating earnings per share from previous practice. Issue 03-6 does not focus on a security holder's contractual rights to ultimately receive the undistributed earnings and net assets of the company upon redemption or liquidation. Instead, it defines participation rights based solely on whether the holder would be entitled to receive any dividends declared during the period, even if the company would not declare any dividends during the period due to economic or practical concerns or legal or contractual limitations on it's the company's ability to pay dividends.

Under Issue 03-6, all securities that meet the definition of a participating security, regardless of whether the securities are convertible, non-convertible, or potential common stock securities, will be considered for inclusion in the computation of basic earnings per share using the two-class method. The application of the two-class method may also have an impact on the diluted earnings per share calculation due to the need to consider each type of potential common shares in the proper sequence to arrive at maximum dilution.

Integra adopted the provisions of Issue 03-6 during the second quarter ended June 30, 2004. The transition provisions of Issue 03-6 require prior period earnings per share amounts to be restated to conform to the new standard, including the impact relating to securities that have been extinguished but were outstanding for a portion of some prior period that is presented for comparative purposes. Accordingly, in the future, Integra will restate its earnings per share calculations for the year ended December 31, 2001 to conform to the two-class method required by Issue 03-6 as it relates to the dividend participation rights included in the Series B and Series C Convertible Preferred Stock that were outstanding during that period. The adoption of Issue 03-6 will reduce previously reported basic earnings per share by \$0.05 to \$1.03 and diluted earnings per share by \$0.02 to \$0.92 in 2001. The adoption of Issue 03-6 will not change the previously reported basic or diluted earnings per share for any other year.

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:

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

Non-Cash Compensation Charges May Affect Our Future Earnings

On March 31, 2004, the FASB issued an Exposure Draft "Share-Based Payment - An Amendment of FASB Statements No. 123 and 95." The Exposure Draft addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally would require instead that such transactions be accounted for using a fair-value based method. The Exposure Draft proposes that the cost of all forms of equity-based compensation granted to employees, excluding employee stock ownership plans, be recognized in a company's income statement and that such cost be measured at the fair value of the stock options. As proposed, the new rules would be applied on a modified prospective basis as defined in the Exposure Draft, and would be effective for fiscal years beginning after December 15, 2004. We are currently evaluating option valuation methodologies and assumptions in light of the evolving accounting standards related to employee stock options. Current estimates of option values using the Black-Scholes method, as disclosed in Note 1 to the unaudited consolidated financial statements in our calculation of pro forma net income as required by FASB 123, may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

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 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. Further, our competitors may be more effective at implementing their technologies to develop commercial products.

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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, we believe that two or more of our large competitors are in the process of introducing an onlay dural graft matrix. The introduction of such products could reduce the sales, growth in sales, and the profitability of our duraplasty products, including our DuraGen(R), DuraGen Plus(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 plastic and reconstructive surgery business is small compared to its principal competitors, which include major medical device and wound care companies such as the ETHICON division of Johnson & Johnson, Smith and Nephew, Inamed, Mentor, and Zimmer. 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 19 businesses or product lines at a total cost of approximately \$160 million.

We may be unable to continue to implement our growth strategy, and our strategy may be ultimately 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 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

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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 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

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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.

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 products, the NeuraGen(TM) Nerve Guide, and the INTEGRA(R) Dermal Regeneration Template, 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 effect on our current business or our ability to expand our business.

The European Union has recently announced that new medical devices containing tissues of animal origin will have to conform to new requirements, and existing medical devices containing animal tissue must be re-assessed between April 1,

2004 and September 30, 2004. We have submitted all documents required for a re-assessment of our products within the schedule required by the European Union. If the required documentation is not approved by September 30, 2004, existing EC Certificates will become invalid.

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 all of our tendon from the United States. We expect to manufacture some of our products from tendon purchased from New Zealand, a country which has never had a case of BSE. If we cannot secure and 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 after September 2004. 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.

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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.

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 certain aspects of many 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 may take several years.

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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 have a policy of requiring 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. 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) and DuraGen Plus(TM) Dural Graft 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) and Ventrix(R)lines of intracranial pressure monitors and catheters.

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While we are not dependent on sole-source suppliers, 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 Ventrix(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 an enterprise resource system for use in all of our facilities. This system will replace several systems on which we now rely. We are also planning to outsource our product distribution function. A delay or other problem 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 against third parties, such as infringement suits or interference proceedings. 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.

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In 2003 and early 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. We currently do not hedge our exposure to foreign currency risk. 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 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 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.

Changes In The Health Care Industry May Require Us To Decrease The Selling Price For Our Products Or 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:

- major third-party payors of hospital 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;
- |X| 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;
- |X| 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;
- |X| 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;
- |X| there is economic pressure to contain health care costs in international markets;
- |X| 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
- |X| 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.

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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:

- |X| 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
- |X| 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. In addition, 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.

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.

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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, 2003 filed with the Securities and Exchange Commission and those set forth under the heading "Factors That May Affect our 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.

# 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 Product Revenues and 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 June 30, 2004 would increase or decrease interest income by approximately \$1.9 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 June 30, 2004, 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 June 30, 2004, the net fair value of the interest rate swap approximated \$2.0 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

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 Chief Executive Officer and Senior Vice President, Finance and Treasurer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any 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.

As required by SEC Rule 13a-15(b), we have carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Treasurer, 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 Chief Executive Officer and Senior Vice President, Finance and Treasurer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

During the second quarter of 2004, the Company's management notified the Company's Audit Committee and PricewaterhouseCoopers, LLP, the Company's

independent auditors, that they had identified a significant deficiency regarding the Company's internal controls over financial reporting. The significant deficiency, which was not considered a material weakness, related to the internal controls associated with cut-off for inter-plant inventory transfers between two specific Company locations. The internal controls did not adequately ensure that inventory received at one of the Company's distribution facilities was relieved from an in-transit inventory account on a timely basis when the items were entered into the detailed inventory subsidiary ledger and recorded in an on-hand inventory account. The Company modified the internal control procedures for these inter-plant transfers and has added an additional layer of review to the cut-off procedures. The Company believes that these actions adequately address the significant deficiency.

No other changes in the Company's internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the second quarter ended June 30, 2004, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

# PART II. OTHER INFORMATION

# ITEM 4. SUBMISSION OF MATTTERS TO A VOTE OF SECURITY HOLDERS

The Company's Annual Meeting of Stockholders was held on May 17, 2004 and in connection therewith, management solicited proxies pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended. An aggregate of 23,284,456 shares of the Company's common stock was outstanding and entitled to a vote at the meeting. At the meeting the following matters (not including ordinary procedural matters) were submitted to a vote of the holders of the common stock, with the results indicated below:

1. Election of directors to serve until the 2005 Annual Meeting. The following persons, all of whom were serving as directors and were management's nominees for election, were elected. There was no solicitation in opposition to such nominees. The tabulation of votes was as follows:

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Withheld -

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<del>David C.</del>
Auth
<del>22,119,627</del>
<del>1,164,829</del>
<del>Keith</del>
<del>Bradley</del>
<del>22,119,627</del>
<del>1,164,829</del>
<del>Richard E.</del>
<del>Caruso</del>
<del>18,847,589</del>
<del>4,436,867</del>
<del>Stuart M.</del>
Essig
<del>22,119,627</del>
<del>1,164,829</del>
Neal
Moszkowski
<del>22,119,627</del>
<del>1,164,829</del>
James M.
Sullivan
<del>22,119,627</del>
<del>1,164,829</del>

2. Approval of Amendment to the Company's 1998 Employee Stock Purchase Plan. The Amendment to the Company's 1998 Employee Stock Purchase Plan was approved. The tabulation of votes was as follows:

For	Against	Abstentions
22,149,793	1,119,383	15,280

3. Ratification of independent auditors. The appointment of PricewaterhouseCoopers LLP as the Company's independent auditors for the current fiscal year was ratified. The tabulation of votes was as follows:

For	Against	Abstentions
23,161,243	116,414	6,799

#### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

- (a) 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 and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as created

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(b) Reports on Form 8-K

On April 27, 2004 we filed a Report on Form 8-K under items 7 and 12 regarding our earnings for the quarter ended March 31, 2004.

# 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: August 9, 2004 /s/ Stuart M. Essig Stuart M. Essig President and Chief Executive Officer Date: August 9, 2004 /s/ David B. Holtz David B. Holtz Senior Vice President,

Finance and Treasurer

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 and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002

# EXHIBIT 31.1

Certification of Principal Executive Officer Pursuant to Section 302 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)) for the registrant and 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 quarterly report is being prepared;
  - b) 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
  - c) 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):
  - 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: August 9, 2004

/s/ Stuart M. Essig

Stuart M. Essig Chief Executive Officer



# EXHIBIT 31.2

Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- 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 officers 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)) for the registrant and 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 quarterly report is being prepared;
  - b) 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
  - c) 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):
  - 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: August 9, 2004

/s/ David B. Holtz

David B. Holtz Senior Vice President, Finance and Treasurer Exhibit 32.1

Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

- The Quarterly Report on Form 10-Q of the Company for the period ending June 30, 2004 (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: August 9, 2004

By: /s/ Stuart M. Essig Stuart M. Essig Chief Executive Officer

Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes -Oxley Act of 2002

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 period ending June 30, 2004 (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: August 9, 2004

By: /s/ David B. Holtz David B. Holtz Sr. Vice President, Finance and Treasurer