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INTEGRA LIFESCIENCES HOLDINGS CORP

Form 8-K

November 08, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): November 7, 2004

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	0-26224	51-0317849
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

311 Enterprise Drive  
Plainsboro, NJ 08536

(Address of principal executive offices) (Zip Code)  
(609) 275-0500 (Registrant's  
telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

ITEM 2.02. Results of Operations and Financial Condition

On November 7, 2004, Integra LifeSciences Holdings Corporation issued a press release announcing financial results for the quarter ended September 30, 2004. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01. Financial Statements and Exhibits.

(c) Exhibits.

Exhibit

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Number	Description of Exhibit
99.1	Press release issued November 7, 2004 regarding earnings for the quarter ended September 30, 2004

This exhibit is being furnished under Item 12, Results of Operations and Financial Condition of this Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

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

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: November 7, 2004

By: /s/ Stuart M. Essig

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Stuart M. Essig  
President and Chief Executive Officer

Exhibit Index

Exhibit Number	Description of Exhibit
99.1	Press release issued November 7, 2004 regarding earnings for the quarter ended September 30, 2004

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Exhibit 99.1

News Release

Contacts:

Integra LifeSciences Holdings Corporation

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## Integra LifeSciences Announces Third Quarter 2004 Financial Results

Plainsboro, New Jersey, November 7, 2004 -- Integra LifeSciences Holdings Corporation (NASDAQ: IART) today reported its third quarter revenues and earnings. Total revenues in the third quarter of 2004 increased by \$12.1 million to \$59.1 million, a 26% increase over the third quarter of 2003. Product revenues increased by \$15.4 million to \$58.9, or 35%, over the prior year period. Excluding recently acquired product lines, third quarter 2004 product revenues increased by \$9.6 million, or 22%, over the prior year period.

We reported a net loss of \$7.6 million, or \$0.25 per share, for the third quarter of 2004, compared to net income of \$6.8 million, or \$0.23 per share, in the third quarter of 2003. During the past quarter, we recorded a \$23.9 million share-based compensation charge on our grant of contract stock units to our President and Chief Executive Officer in connection with the extension of his employment agreement, a \$1.4 million in-process research and development charge in connection with our making of a milestone payment to a third-party developer, a \$0.8 million incremental tax pcharge incurred in connection with the reorganization of certain European operations, and a \$0.5 million charge relating to a license payment for technology under development. Excluding these special charges, net earnings for the third quarter of 2004 were \$8.7 million, or \$0.28 per share.

"I am very pleased with our performance in the third quarter," said Stuart M. Essig, Integra's President and Chief Executive Officer, "as we once again produced organic revenue growth of over 20%, with particularly strong performances from the DuraGen(R) and DuraGen Plus(TM) products, the INTEGRA(R) Dermal Regeneration Template and the INTEGRA(TM) Bilayer Matrix Wound Dressing. In addition, we have positioned ourselves for continued growth through our recent introduction of new and innovative products, such as the DuraGen Plus(TM) Adhesion Barrier Matrix, the NeuroSensor(R) Cerebral Blood Flow and IntraCranial Pressure System, the NPH(TM) Low Flow Hydrocephalus Valve, the INTEGRA(TM) Matrix Wound Dressing, the INTEGRA(TM) Dermal Regeneration Template - Terminally Sterilized and the KraniOS(TM) Cranial Closure System."

Our revenues for the periods were as follows:

Three Months		Nine
Ended September 30,		Ended Sep
2004	2003	2004
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Product Revenue:			
Neuromonitoring products	\$12,689	\$11,679	\$35,700
Operating room products	20,823	13,555	58,566
Instruments	19,933	13,141	54,982
Private label products	5,412	5,092	17,480
	-----	-----	-----
Total Product Revenue	58,857	43,467	166,728
Other revenue	273	3,591	1,286
	-----	-----	-----
Total Revenue	\$59,130	\$47,058	\$168,014

Increased sales of our intracranial monitoring products, including our Camino(R) and LICOX(R) monitoring systems, provided most of the year-over-year growth in neuromonitoring product revenues.

Continued strong growth in sales of our DuraGen and DuraGen Plus Dural Graft Matrix products and direct selling of the INTEGRA Dermal Regeneration Template and INTEGRA Bilayer Matrix Wound Dressing accounted for most of the increase in operating room product revenues.

Sales of recently acquired product lines contributed \$5.8 million of the year-over-year increase in instrument revenues for the third quarter. Increased sales of our JARIT(R) and Ruggles(TM) surgical instrument lines provided the remainder of the growth in instrument product revenues.

The increase in revenues attributable to our remaining private label products, including the Absorbable Collagen Sponge that we supply for use in Medtronic's INFUSE(TM) bone graft product, more than offset the removal of INTEGRA Dermal Regeneration Template revenues from our private label products category.

Changes in foreign currency exchange rates contributed \$0.6 million to our year-over-year product revenue growth.

Gross margin on product revenues in the third quarter of 2004 was 62%. Our gross margin was positively affected by changes in the mix of our products sold during the quarter and by the resumption of direct sales of the INTEGRA Dermal Regeneration Template.

General and administrative expense increased \$26.3 million in the third quarter of 2004 to \$30.1 million, largely due to the share-based compensation charge recorded with respect to the grant of contract stock units to our President and Chief Executive Officer in connection with the renewal of his employment agreement. Research and development expense increased from \$2.6 million in the third quarter of 2003 to \$5.1 million in the current period primarily as a result of a \$1.4 million dollar in-process research and development charge in connection with a milestone payment to a third-party developer and a \$0.5 million license fee charge. Sales and marketing expense increased by \$2.4 million to \$12.5 million in the third quarter of 2004, but decreased as a percentage of product sales to 21% from 23% in the prior year period.

We reported net interest income of \$243,000 in the third quarter of 2004, as compared to net interest expense of \$188,000 in the prior year period. Third quarter results also reflect an increase in our annual effective tax rate to 39%, largely attributable to an incremental tax charge recorded in the period.

We repurchased 500,000 shares of our common stock at an average price of \$28.48 in the period and had cash and investments totaling \$191.0 million at September 30, 2004.

We are updating our expectations for revenues, gross margin and earnings per

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share for 2004 and 2005. In accordance with our usual practice, our expectations for 2004 and 2005 financial performance do not include the impact of acquisitions or other strategic corporate transactions that have not yet closed.

Subsequent to Integra's issuance of contingent convertible notes in 2003, the Emerging Issues Task Force (EITF) Issue 04-08 proposed that the unissued shares underlying contingent convertible notes be treated as if such shares were issued and outstanding for the purposes of calculating earnings per share if such impact would be dilutive. On October 13, 2004, the Financial Accounting

Standards Board (FASB) ratified this new accounting treatment for periods ending after December 15, 2004. Consequently, Integra will reflect the dilutive effect of its contingent convertible senior notes on earnings per share in the fourth quarter of 2004.

It is important to note that our \$120 million of contingent convertible senior notes can convert into 3.5 million shares of our common stock at any time that our common stock trades above \$37.56 per share. The ratification of EITF Issue 04-08 will have no effect on Integra's operating results, revenues, net income or cash position as reported in our fourth quarter 2004, and full year 2004 and 2005 guidance. Rather, it requires a revised method of calculating earnings per share. In order to provide clarity, we are providing guidance both before and after the effects of the new pronouncement.

Our guidance for the fourth quarter of 2004 is for total revenues in the range of \$60 million to \$63 million and earnings per share of \$0.29 to \$0.31, before giving effect to the change in accounting for our convertible contingent senior notes and the increase in our effective tax rate to 39%. Including the effect of the EITF Issue 04-08 and the increase in our effective tax rate for 2004, earnings per diluted share are expected to be between \$0.27 and \$0.29.

We expect total revenues of between \$270 million and \$280 million in 2005. Consolidated gross margin is expected to be 64%. We expect our earnings to be within a range of \$1.42 to \$1.47 per share in 2005 before the change in accounting for the company's contingent convertible notes. Including this accounting change, earnings per diluted share for 2005 are expected to be between \$1.35 and \$1.39.

We have scheduled a conference call for 9:00 am EDT tomorrow, November 8, 2004, to discuss the financial results for the third quarter of 2004 and forward-looking financial guidance. The call is open to all listeners and will be followed by a question and answer session. Access to the live call is available by dialing (973) 582-2732 or through a listen-only webcast via a link provided on the home page of Integra's website at [www.Integra-LS.com](http://www.Integra-LS.com). A replay of the conference call will be accessible starting one hour following the live event. Access to the replay is available through November 22, 2004 by dialing (973) 341-3080 (access code 4865983) or through the webcast accessible on our home page.

Integra LifeSciences Holdings Corporation is a diversified medical technology company that develops, manufactures, and markets medical devices for use in a variety of applications. The primary applications for our products are neuro-trauma and neurosurgery, plastic and reconstructive surgery and general surgery. Integra is a leader in applying the principles of biotechnology to medical devices that improve patients' quality of life. Our corporate headquarters are in Plainsboro, New Jersey, and we have research, manufacturing and distribution facilities located throughout the world. We have approximately 1,200 employees. Please visit our website at (<http://www.Integra-LS.com>).

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning future financial

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performance, including projections for revenues, gross margins, earnings per share and cash flows. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results. Among other things, our ability to maintain relationships with customers of acquired entities, physicians' willingness to adopt our recently launched and planned products and our ability to secure regulatory approval for products in development may adversely affect our future product revenues; our ability to increase sales and product volumes may adversely affect our future gross margins; our ability to integrate acquired businesses, increase product sales and gross margins, and control non-product costs may affect our earnings per share; and our future net income results and our ability to effectively manage working capital may affect our future cash flows. In addition, the economic, competitive, governmental, technological and other factors identified under the heading "Factors That May Affect Our Future Performance" included in the Business section of Integra's Annual Report on Form 10-K for the year ended December 31, 2003 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

Regulation G, "Conditions for Use of Non-GAAP Financial Measures," and other provisions of the Securities Exchange Act of 1934, as amended, define and prescribe the conditions for the use of certain non-GAAP financial information. In this news release, we provide "growth in product revenues excluding recently acquired product lines", which is a non-GAAP financial measure. A reconciliation of this non-GAAP financial measure to the most comparable GAAP measure is provided in the tables of financial information contained at the end of this news release.

Non-GAAP financial measures should not be relied upon to the exclusion of GAAP financial measures. Management believes that this non-GAAP financial measure is important supplemental information to investors which reflects an additional way of viewing aspects of our operations that, when viewed with our GAAP results and the accompanying reconciliations, provides a more complete understanding of factors and trends affecting our ongoing business and operations. Management strongly encourages investors to review our financial statements and filed reports in their entirety and to not rely on any single financial measure. Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names.

### INTEGRA LIFESCIENCES HOLDINGS CORPORATION (In thousands, except per share data) (UNAUDITED)

#### Statement of Operations Data:

	Three Months Ended September 30, 2004		
	Reported	Special Charges	Before Special Charges
Product revenues	\$58,857		\$58,857
Other revenues	273		273
	-----		-----
Total revenues	59,130		59,130

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Cost of product revenues	22,412		22,412
Research and development	5,103	1,900	3,203
Sales and marketing	12,488		12,488
General and administrative	30,112	23,876	6,236
Amortization	1,195		1,195
	-----		-----
Total costs and expenses	71,310	25,776	45,534
Operating income (loss)	(12,180)	25,776	13,596
Interest income (expense), net	243		243
Other income (expense), net	306		306
	----		----
Income (loss) before income taxes	(11,631)	25,776	14,145
Provision (benefit) for income taxes (1)	(4,034)	9,504	5,470
	-----	-----	-----
Net income (loss)	\$ (7,597)	\$16,272	\$8,675
Diluted earnings (loss) per share	\$ (0.25)		\$0.28
Diluted weighted average common shares outstanding	30,326		31,256

(In thousands, except per share data)  
(UNAUDITED)

Statement of Operations Data:

	Nine Months Ended September 30, 2004		
	Reported	Special Charges	Before Special Charges
Product revenues	\$166,728		\$166,728
Other revenues	1,286		1,286
	-----		-----
Total revenues	168,014		168,014
Cost of product revenues	64,078		64,078
Research and development	10,565	1,900	8,665
Sales and marketing	36,799		36,799
General and administrative	42,297	23,876	18,421
Amortization	3,127		3,127
	-----		-----
Total costs and expenses	156,866	25,776	131,090
Operating income	11,148	25,776	36,924

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Interest income (expense), net	460		460
Other income (expense), net	424		424
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Income before income taxes	12,032	25,776	37,808
Provision for income taxes (1)	4,674	9,504	14,178
	-----	-----	-----
Net income	\$7,358	\$16,272	\$23,630
Diluted earnings per share	\$0.24		\$0.76
Diluted weighted average common shares outstanding	31,026		31,026

(1) The income tax adjustment is the result of excluding the tax impact of the special charges reflected above and the incremental tax charge recorded in connection with the European reorganization. These adjustments resulted in an annualized effective tax rate of 37.5%.

Condensed Balance Sheet Data:

	September 30, 2004	December 31, 2003
<	-----	-----
Cash and marketable securities, including non-current portion	\$190,998	\$206,743
Accounts receivable, net	38,028	28,936
Inventory, net	52,400	41,046
Total assets	440,187	412,526
Current liabilities	23,766	20,618
Long-term debt	119,220	119,257
Total liabilities	147,552	143,996
Stockholders' equity	292,635	268,530

Reconciliation of non-GAAP financial measure to the most comparable GAAP measure:

Growth in product revenues excluding recently acquired product lines

Excluding recently acquired product lines, third quarter 2004 product revenues increased by \$9.6 million, or 22%, over the prior year period.

	Quarter Ended September 30, 2004	September 30, 2003	Increase (Decrease) \$	%
	-----	-----	-----	-----
	(\$ in thousands)			
Total product revenues, as reported	\$ 58,857	\$ 43,467	\$15,390	35%



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Less: Product revenues acquired since the beginning of the third quarter of 2003	5,833	21	5,812	NM
	-----	-----	-----	-----
Product revenues excluding acquired products	\$ 53,024	\$ 43,446	\$9,578	22%

Source: Integra LifeSciences Holdings Corporation