

INTEGRA LIFESCIENCES HOLDINGS CORP

Form 8-K

July 27, 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): July 27, 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 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(a) Not applicable

(b) Not applicable

(c) Exhibits.

Exhibit

Number	Description of Exhibit
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99.1	Press release issued July 27, 2004 regarding earnings for the quarter ended June 30, 2004
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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.

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ITEM 12. Results of Operations and Financial Condition

On July 27, 2004, Integra LifeSciences Holdings Corporation issued a press release announcing financial results for the quarter ended June 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.

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: July 27, 2004

By: /s/ Stuart M. Essig

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Stuart M. Essig  
President and Chief Executive Officer

Exhibit Index

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Exhibit Number	Description of Exhibit
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99.1	Press release issued July 27, 2004 regarding earnings for the quarter ended June 30, 2004
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Exhibit 99.1

News Release

Contacts:

Integra LifeSciences Holdings Corporation

John Bostjancic  
Senior Director of Finance  
(609) 936-2239  
jbostjancic@integra-ls.com

Maria Platsis  
Director of Corporate Development  
and Investor Relations  
(609) 936-2333  
mplatsis@integra-ls.com

### Integra LifeSciences Announces Second Quarter 2004 Financial Results

Plainsboro, New Jersey, July 27, 2004 -- Integra LifeSciences Holdings Corporation (NASDAQ: IART) today reported net income of \$7.5 million, or \$0.24 per share, for the second quarter of 2004, compared to net income of \$5.4 million, or \$0.18 per share, in the second quarter of 2003, a 33% increase in earnings per share over the prior year period.

Total revenues in the second quarter of 2004 increased by \$13.7 million to \$56.4 million, a 32% increase over the second quarter of 2003, as product revenues increased by \$15.2 million to \$56.4 million and other revenues decreased by \$1.5 million.

Excluding recently acquired product lines, second quarter 2004 product revenues increased by \$11.0 million, or 27%, over the prior year period.

Operating income for the period was \$11.6 million, a 40% increase over the second quarter of 2003.

"I am pleased with our performance in the second quarter," said Stuart M. Essig, Integra's President and Chief Executive Officer. "In particular, our organic revenue growth exceeded our expectations this quarter, 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. JARIT(R) also had a very strong quarter, leading our instrument revenues to 20% organic growth versus the prior year period. We also completed two acquisitions during the quarter, which enhanced our neurosurgical product offerings and our distribution capabilities outside the United States."

In May we acquired the MAYFIELD(R) Cranial Stabilization and Positioning Systems and the BUDDE(R) Halo Retractor System from Schaerer Mayfield USA, Inc. (formerly Ohio Medical Instrument Company). The acquired operations include 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. We market these products through our Integra NeuroSciences sales force.

In May we also acquired Berchtold Medizin-Elektronik GmbH, now named Integra ME, from Berchtold Holding GmbH. Based in Tuttlingen, Germany, Integra ME manufactures and markets the Elektrotom(R) line of electrosurgery generators and the Sonotom(TM) ultrasonic surgical aspirator, as well as a broad line of

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related handpieces, instruments and disposables used in many surgical procedures, including neurosurgery. We market these products to hospitals and physicians primarily through a network of distributors.

Our revenues for the periods were as follows:

	Three Months Ended June 30,		Six Mo Ended Ju
	2004	2003	2004
	----	----	----
Product Revenue:			
Neuromonitoring products	\$11,813	\$10,552	\$23,011
Operating room products	19,412	12,833	37,744
Instruments	19,006	12,358	35,049
Private label products	6,205	5,494	12,068
	- - - - -	- - - - -	- - - - -
Total Product Revenue	56,436	41,237	107,872
Other revenue	5	1,499	1,013
	- - - - -	- - - - -	- - - - -
Total Revenue	\$56,441	\$42,736	\$108,885

Increased sales of our intracranial monitoring products and drainage systems provided most of the year-over-year growth in neuromonitoring product revenues.

Continued strong growth in sales of our DuraGen(R) and DuraGen Plus(TM) Dural Graft Matrix products and direct selling of the INTEGRA(R) Dermal Regeneration Template accounted for the increase in operating room product revenues.

Sales of recently acquired product lines contributed \$4.2 million of the year-over-year increase in instrument revenues for the second quarter. Increased sales of our JARIT(R) and Ruggles(TM) surgical instrument lines and of our ultrasonic aspirator products contributed the remainder of the growth in instrument product revenues.

The increase in our private label product revenues attributable to 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 this category.

Changes in foreign currency exchange rates contributed \$0.5 million to our year-over-year product revenue growth.

Gross margin on product revenues in the second 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.

Research and development expense decreased slightly from \$2.8 million in the second quarter of 2003 to \$2.6 million in the current period. Sales and marketing expense increased by \$4.1 million to \$13.2 million in the second quarter of 2004. This increase was due to the continued expansion of the Integra NeuroSciences and the Integra Plastic and Reconstructive Surgery U.S.-based sales forces, increased marketing headcount and spending particularly to support plastic and reconstructive surgery product lines, and additional spending to support the MAYFIELD and Berchtold product lines. General and administrative expense increased \$1.6 million in the second quarter of 2004 to \$6.3 million.

We reported net interest income of \$160,000 in the second quarter of 2004, as compared to net interest expense of \$198,000 in the prior year period.

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The Company generated \$9.7 million in cash flows from operations in the second quarter of 2004.

The Company's cash and investments totaled \$194 million at June 30, 2004.

In the second half of 2004, we expect to incur approximately \$1.5 million of charges as a result of the Mayfield acquisition, including inventory fair value purchase accounting costs, facilities consolidation expenses, and distributor termination payments, and related to the planned relocation of our National Distribution Center from Plainsboro, New Jersey to Reno, Nevada in the fourth quarter. We have revised our guidance for the third and fourth quarters of 2004 to reflect these additional anticipated expenses.

In addition, our revised guidance excludes the impact of the \$14.9 million after-tax non-cash compensation charge related to the contract stock units granted in connection with the renewal of our Chief Executive Officer's employment agreement in the third quarter of this year. Our guidance also excludes a potential in-process research and development charge related to a \$1.5 million milestone payment that may become due in connection with a product development agreement.

Finally, 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.

We are updating our expectations for revenues, gross margin and earnings per share for 2004 and 2005. We expect total revenues of between \$227 million and \$232 million in 2004 and \$270 million and \$280 million in 2005. Consolidated gross margin is expected to be 61% and 63% of product revenues in 2004 and 2005, respectively. We expect our earnings to be within a range of \$1.05 to \$1.10 per share in 2004 and \$1.42 and \$1.47 per share in 2005. Our guidance for the third quarter of 2004 is for total revenues in the range of \$58 million to \$60 million and earnings per share of \$0.26 to \$0.28.

We have scheduled a conference call for 9:00 am EDT tomorrow, July 28, 2004, to discuss the financial results for the second 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 August 11, 2004 by dialing (973) 341-3080 (access code 4865967) 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 1,100 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 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

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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  
CONSOLIDATED FINANCIAL RESULTS  
(In thousands, except per share data)  
(UNAUDITED)

Statement of Operations Data:

	Three Months Ended June 30,		
	2004	2003	
	----	----	
Product revenues	\$56,436	\$41,237	\$1
Other revenues	5	1,499	
	-----	-----	
Total revenues	56,441	42,736	1

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Cost of product revenues	21,665	17,090
Research and development	2,639	2,777
Sales and marketing	13,160	9,082
General and administrative	6,328	4,736
Amortization	1,049	762
	-----	-----
Total costs and expenses	44,841	34,447
Operating income	11,600	8,289
Interest income (expense), net	160	(198)
Other income (expense), net	135	451
	---	----
Income before income taxes	11,895	8,542
Provision for income taxes	4,377	3,124
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Net income	\$7,518	\$5,418
Diluted earnings per share	\$0.24	\$0.18
Diluted weighted average common shares outstanding	30,964	30,061

Condensed Balance Sheet Data:

	June 30, 2004 -----	December 31, 2003 ----
Cash and marketable securities, including non-current portion	\$194,250	\$206,743
Accounts receivable, net	35,622	28,936
Inventory, net	50,509	41,046
Total assets	433,577	412,526
Current liabilities	23,184	20,618
Long-term debt	118,336	119,257
Total liabilities	147,128	143,996
Stockholders' equity	286,449	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, second quarter 2004 product revenues increased by \$11.0 million, or 27%, over the prior year period.

Quarter Ended June 30, 2004	2003	Increase (Decrease) \$	%
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(\$ in thousands)			

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Total product revenues, as reported	\$ 56,436	\$ 41,237	\$15,199	37%
Less: Product revenues acquired in 2004 and 2003	4,230	--	4,230	NM
	-----	-----	-----	-----
Product revenues excluding acquired products	\$ 52,206	\$ 41,237	\$10,969	27%

"MAYFIELD" is a registered trademark of SM USA, Inc., a wholly owned subsidiary of Schaerer Mayfield USA, Inc.

Source: Integra LifeSciences Holdings Corporation