

INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
February 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): February 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 (Commission File Number) (I.R.S. Employer
incorporation or organization) 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

99.1 Press release issued February 27, 2004 regarding earnings for the quarter
and year ended December 31, 2003

This exhibit is being furnished under Item 12, Results of Operations and
Financial Condition of this Form 8-K and shall not be deemed 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 February 27, 2004, Integra LifeSciences Holdings Corporation issued a press release announcing its financial results for the quarter and year ended December 31, 2003 and held a conference call to discuss those results and its forward looking guidance. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. A replay of the conference call is available through March 12, 2004 by telephone at (973)341-3080 (access code 4418658) or by webcast at www.integra-ls.com.

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: February 27, 2004 By: /s/ Stuart M. Essig

Stuart M. Essig
President and Chief Executive Officer

Exhibit Index

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99.1 Press release issued February 27, 2004 regarding earnings for the quarter and year ended December 31, 2003

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Exhibit 99.1

News Release

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Integra LifeSciences Reports Record Operating Earnings and Revenues for the Fourth Quarter and Full Year 2003

Plainsboro, New Jersey, February 27, 2004 -- Integra LifeSciences Holdings Corporation (Nasdaq: IART) today reported net income of \$9.2 million, or \$0.30 per share, for the fourth quarter of 2003, compared to \$25.4 million, or \$0.83 per share, for the prior year period. Net income for the year ended December 31, 2003 was \$26.9 million, or \$0.88 per share, compared to \$35.3 million, or \$1.14 per share, for the year ended December 31, 2002. Our reported net income for the quarter and year ended December 31, 2002 included a \$20.4 million tax benefit attributable to a reduction in deferred tax asset valuation allowances.

Operating income was \$13.0 million for the fourth quarter of 2003, a 92% increase over the fourth quarter of 2002, and \$39.6 million for the year ended December 31, 2003, a 107% increase over 2002.

Total revenues in the fourth quarter of 2003 increased by \$23.8 million to \$59.0 million, a 67% increase over the fourth quarter of 2002. Product revenues increased by \$12.8 million to \$46.9 million, a 37% increase over the fourth quarter of 2002, and other revenues increased by \$11.0 million to \$12.2 million. The increase in other revenues in the fourth quarter reflects accelerated recognition of deferred revenue associated with the termination of our 1999 supply and distribution agreement for the INTEGRA(R) Dermal Regeneration Template with ETHICON Inc.

"I am pleased with our performance in the fourth quarter and for the year," said Stuart M. Essig, Integra's President and Chief Executive Officer. "We achieved record revenues and operating income and invested in a number of initiatives that will support the continued growth of the Company. During the fourth quarter, we completed two acquisitions, extended our line of dural matrix products, significantly expanded our marketing capability, doubled our plastic and reconstructive surgery sales organization, initiated an upgrade of our corporate information systems, consolidated our San Diego facilities and made a significant contribution to the Integra Foundation."

As a result of the termination of the agreement with ETHICON Inc., we obtained the exclusive right to sell the INTEGRA Dermal Regeneration Template effective January 1, 2004. In anticipation of the return of this product, we reorganized and significantly expanded our plastic and reconstructive surgery sales force in the fourth quarter. We now distribute the INTEGRA Dermal Regeneration Template, along with a line of specialized surgical instruments and implants, through a fourteen-person plastic and reconstructive surgery sales organization in the United States and parts of Western Europe and through a network of distributors elsewhere. We expect to further increase the size of this sales organization in 2004.

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In November we acquired Spinal Specialties, Inc., a producer of custom kits and products used in a variety of spinal, orthopedic and pain management procedures, for approximately \$6.0 million in cash. Spinal Specialties' products include the OsteoJect(TM) Bone Cement Delivery System, which allows precise delivery of bone cement to a surgical site under active fluoroscopy by a surgeon whose hands remain outside the fluoroscopy field, and the ACCU-DISC(TM) Pressure Monitoring System, which offers the accurate delivery of fluids to the body and the ability to monitor the fluids in discography interpretation. Spinal Specialties markets its products to anesthesiologists and interventional radiologists through an in-house telemarketing team and a network of distributors.

In December we acquired the assets of Reconstructive Technologies, Inc., the developer of the Automated Cyclic Expansion or ACE System(TM), a tissue expansion device. The ACE System uses a compact pump that produces a cyclic force when attached to ballooning tissue expanders. The ACE System is designed to accelerate tissue expansion by stimulating the body's natural response to physical stress on the skin. We anticipate obtaining regulatory clearance and launching the product through our plastic and reconstructive sales force in 2005.

Our revenues for the period were as follows:

	Three Months Ended December 31,		Year Ended December 31,	
	2003	2002	2003	2002
Product Revenue				
Neuromonitoring products	\$11,466	\$10,479	\$44,229	\$37,184
Operating room products	14,325	11,865	53,301	38,326
Instruments	15,422	5,780	47,168	16,802
Private label products	5,648	5,978	21,997	20,313
Total Product Revenue	46,861	34,102	166,695	112,625
Other revenue	12,164	1,159	18,904	5,197
Total Revenue	59,025	35,261	185,599	117,822

Increased sales of our intracranial monitoring products and drainage systems provided most of the fourth quarter year-over-year growth in neuromonitoring product revenues. Continued strong growth in sales of our DuraGen(R) Dural Graft Matrix and NeuraGen(TM) Nerve Guide products accounted for the increase in operating room product revenues. Sales of the recently acquired JARIT(R) and Padgett(TM) surgical instrument lines and of Spinal Specialties' product lines contributed \$9.0 million of the fourth quarter year-over-year increase in instrument revenues. The decline in our private label product revenues is attributable to a decline in revenues from the Absorbable Collagen Sponge we supply for use in Medtronic's INFUSE(TM) bone graft product.

Revenues from product lines acquired since the beginning of 2002 accounted for \$37.6 million of the increase in product revenues for the year ended December 31, 2003, as compared to 2002. Excluding revenues attributable to private label product lines and to product lines acquired since the beginning of 2002, product revenues for the year ended December 31, 2003 increased by \$16.1 million, or 19%, over 2002. Changes in foreign currency exchange rates contributed \$2.0 million to our annual year-over-year product revenue growth.

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Revenues from product lines acquired since the beginning of the fourth quarter of 2002 accounted for \$9.3 million of the increase in product revenues in the fourth quarter of 2003, as compared to the fourth quarter of 2002. Excluding revenues attributable to private label product lines and to product lines acquired since the beginning of the fourth quarter of 2002, fourth quarter product revenues increased by \$3.8 million, or 14%, over the fourth quarter of 2002. Changes in foreign currency rates contributed \$0.7 million to our quarterly year-over-year product revenue growth.

"The income we recognized in connection with the termination of our agreement with ETHICON in the fourth quarter provided us with a unique opportunity to invest in our business," said Stuart Essig. "We initiated and completed a significant number of activities during the quarter, which resulted in higher operating costs compared to our recent trend. We anticipate our 2004 operating costs as a percentage of product revenues to return to levels consistent with the first three quarters of 2003."

Gross margin on product revenues in the fourth quarter of 2003 was 55%. The current quarter included approximately \$1.2 million of inventory write-offs associated with discontinued product lines, raw material quality issues and product packaging changes made to accommodate the direct sales and marketing of the INTEGRA Dermal Regeneration Template product line and discretionary operating expenses. Our gross margin was also negatively affected by the appreciation in the euro and British pound. Starting in the first quarter of 2004, we expect our direct sale and marketing of the INTEGRA Dermal Regeneration Template product line to improve our gross margin, partially offsetting any continued negative effect of a strong euro and pound.

Research and development expense increased \$2.3 million in the fourth quarter of 2003 to \$4.8 million. This increase was primarily due to approximately \$0.9 million of incremental costs incurred in connection with the closing of our San Diego research center and the transfer of many of its activities to other of our facilities, a \$0.4 million in-process research and development charge taken in connection with the acquisition of Reconstructive Technologies, Inc., and \$0.3 million of accelerated spending on sponsored clinical research and publications.

Sales and marketing expense increased by \$4.6 million to \$11.3 million in the fourth quarter of 2003, and as a percentage of product revenue increased from 20% in the fourth quarter of 2002 to 24% in the current period. This increase in sales and marketing expense as a percentage of product revenue is due to increased discretionary spending in anticipation of increased revenues in future periods. We incurred significant costs to expand our sales and marketing infrastructure, particularly in our plastic and reconstructive surgery organization.

General and administrative expense increased \$3.5 million in the fourth quarter of 2003 to \$8.0 million. The increase resulted primarily from a \$2.0 million donation to the Integra Foundation, and \$0.6 million of costs related to discretionary compensation programs.

We reported net interest income of \$81,000 in the fourth quarter of 2003, as compared to \$727,000 in the prior year period. This change resulted primarily from interest expense associated with the \$120.0 million of contingent convertible subordinated notes that we issued in March and April of 2003.

Other income increased to \$2.0 million as a result of the termination payment received from ETHICON, Inc.

Our effective tax rate increased to 37.8% for 2003 primarily as a result of a

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change in the geographic mix of taxable income for 2003, including the effects of the additional revenue and gains associated with the termination of our distribution agreement with ETHICON Inc.

The Company's cash and investments totaled \$206.7 million at December 31, 2003.

We are revising our expectations for revenues, product revenues, gross margin and earnings per share for 2004 and providing our initial guidance for 2005. We are increasing our guidance for total revenues to between \$215 and \$220 million in 2004 and \$250 and \$260 million in 2005. Consolidated gross margin is expected to increase to 61% and 63% of product revenues in 2004 and 2005, respectively. Excluding a potential in-process research and development charge related to a \$1.5 million milestone payment that may become due under the terms of a product development agreement, we expect our earnings to be within a range of \$1.08 to \$1.14 per share in 2004 and \$1.35 to \$1.40 per share in 2005. Our guidance for the first quarter of 2004 is for total revenues in the range of \$50 to \$52 million and earnings per share of \$0.23 to \$0.24.

Our guidance incorporates the expected impact of our recently announced acquisitions of the Sparta and the R&B product lines. 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 have scheduled a conference call for 9:00 am EST today, February 27, 2004, to discuss the financial results for the fourth quarter of 2003 and to further discuss 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) 935-8511 or through a listen-only webcast via a link provided on the home page of Integra's website at 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 March 12, 2004 by dialing (973) 341-3080 access code 4418658) 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 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 manufacturing and research facilities located throughout the world. We have approximately 880 permanent 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, operating expenses, income tax rates, earnings per share and future acquisitions. 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 and changes in foreign currency exchange rates may adversely affect our future gross margins; our ability to integrate recently acquired businesses may affect our operating expenses; the geographic mix of our taxable income may adversely affect our income tax rates; and our ability to integrate acquired businesses, increase product sales and gross

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margins, and control non-product costs may affect our earnings per share. In addition, the economic, competitive, governmental, technological and other factors identified under the heading "Risk Factors" included in the Business section of Integra's Annual Report on Form 10-K for the year ended December 31, 2002 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 private label products and 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, provide 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:

E	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2003	2002	2003	2002
Product revenue	\$46,861	\$34,102	\$166,695	\$112,625
Other revenue	12,164	1,159	18,904	5,197
Total revenue	59,025	35,261	185,599	117,822
Cost of product revenue	20,935	14,168	70,597	45,772
Research and development	4,371	2,471	12,414	9,189
In-process research and development	400	--	400	2,328
Sales and marketing	11,349	6,798	38,097	25,118
General and administrative	8,007	4,539	21,364	14,584
Amortization	968	505	3,080	1,644
Total costs and expenses	46,030	28,481	145,952	98,635
Operating income	12,995	6,780	39,647	19,187
Interest income, net	81	727	471	3,535
Other income (expense), net	1,962	(18)	3,071	3

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Income before income taxes	15,038	7,489	43,189	22,725
Provision for income taxes	5,867	(17,885)	16,32	(12,552)
Net income	\$ 9,171	\$25,374	\$26,861	\$35,277
Diluted earnings per share	\$ 0.30	\$ 0.83	\$ 0.88	\$ 1.14
Diluted weighted average common shares outstanding	30,660	30,659	30,468	30,895

Condensed Balance Sheet Data:

	December 31, 2003	December 31, 2002
Cash and marketable securities, including non-current portion	\$206,743	\$132,311
Accounts receivable, net	28,936	19,412
Inventory, net	41,046	28,502
Total assets	412,525	274,668
Current liabilities	20,082	21,921
Long-term debt	119,257	--
Total liabilities	143,994	27,071
Stockholders' equity	268,530	247,597

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

A. Annual year-over-year growth in product revenues excluding private label products and recently acquired product lines

Excluding revenues attributable to private label product lines and to product lines acquired since the beginning of 2002, product revenues for the year ended December 31, 2003 increased by \$16.1 million, or 19%, over 2002.

	Year Ended December 31, 2003 2002		Increase (Decrease) \$ %	
	-----	-----	-----	-----
	(\$ in thousands)			
Total product revenues, as reported	\$166,695	\$112,625	\$54,070	48%
Less: Product revenues acquired in 2003	24,476	--	24,476	N/A
Product revenues acquired in 2002	20,739	7,607	13,132	173%
Private label product revenues(1)	19,225	18,895	330	2%
	-----	-----	-----	-----
Product revenues excluding acquired products and private label products	\$102,255	\$ 86,123	\$16,132	19%

(1) Excludes private label product revenues already reported in "Product revenues acquired in 2002" and "Product revenues acquired in 2003".

B. Excluding revenues attributable to private label product lines and to product lines acquired since the beginning of the fourth quarter of 2002,

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fourth quarter product revenues increased by \$3.8 million, or 14%, over the fourth quarter of 2002.

	Quarter Ended December 31, 2003 2002		Increase (Decrease) \$ %	
	-----		-----	
	(\$ in thousands)			
Total product revenues, as reported	\$ 46,861	\$ 34,102	\$12,759	37%
Less: Product revenues acquired in 2003	8,595	--	8,595	N/A
Product revenues acquired in the fourth quarter of 2002	1,914	1,185	729	62%
Private label product revenues	5,648	5,978	(330)	(6%)
	-----	-----	-----	-----
Product revenues excluding acquired products and private label products	\$ 30,704	\$ 26,939	\$ 3,765	14%