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INTEGRA LIFESCIENCES HOLDINGS CORP

Form 8-K

October 31, 2003

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): October 31, 2003

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 October 31, 2003 regarding earnings for the
quarter ended September 30, 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 "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 October 31, 2003, Integra LifeSciences Holdings Corporation issued a press release announcing financial results for the quarter ended September 30, 2003. 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: October 31, 2003

By: /s/ Stuart M. Essig

Stuart M. Essig

President and Chief Executive Officer

Exhibit Index

Exhibit Number	Description of Exhibit
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99.1	Press release issued October 31, 2003 regarding earnings for the quarter ended September 30, 2003
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Exhibit 99.1

News Release

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Integra LifeSciences Reports Record Operating Earnings and Revenues for the Third Quarter 2003

Plainsboro, New Jersey, October 31, 2003 -- Integra LifeSciences Holdings Corporation (Nasdaq: IART) today reported net income of \$6.8 million, or \$0.23 per share, for the third quarter of 2003, as compared to net income of \$1.6 million, or \$0.05 per share, in the third quarter of 2002.

Total revenues in the third quarter of 2003 increased by \$16.9 million to \$47.1 million, a 56% increase over the third quarter of 2002, as product revenues increased by \$14.2 million to \$43.5 million and other revenues increased by \$2.6 million to \$3.6 million. Other revenues in the third quarter included a \$2.5 million event payment from ETHICON Inc. for the achievement of various regulatory objectives for the INTEGRA(R) Dermal Regeneration Template.

Operating income for the period was \$10.9 million, a more than fivefold increase over the third quarter of 2002.

"I am pleased with our performance in the third quarter," said Stuart M. Essig, Integra's President and Chief Executive Officer. "We achieved record revenues and operating income while continuing to position the Company for sustained growth. During the quarter, we added significantly to our marketing infrastructure by increasing the number of product managers and support staff."

In September, we amended our 1999 supply and distribution agreement for the INTEGRA Dermal Regeneration Template with ETHICON Inc. to provide for the return to Integra on January 1, 2004 of the exclusive right to sell, market and distribute the INTEGRA product. We also resolved our disagreement with ETHICON Inc. regarding the attainment of certain clinical and regulatory events under the 1999 agreement and recorded a \$2.5 million event payment in connection with the attainment of those events. We intend to distribute the INTEGRA Dermal Regeneration Template through our plastic and reconstructive surgery sales force.

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In August we acquired the assets of Tissue Technologies, Inc., the manufacturer and distributor of the UltraSoft(TM) line of facial implants for soft tissue augmentation of the facial area. We market the UltraSoft products directly to cosmetic and reconstructive surgeons through our plastic and reconstructive surgery sales force.

On October 28, 2003, we agreed to acquire Spinal Specialties, Inc. from I-Flow Corporation (Nasdaq: IFLO) for approximately \$6.0 million in cash. Spinal Specialties assembles and sells custom kits and products for chronic pain management, including the OsteoJect(TM) Bone Cement Delivery System and the ACCU-DISC(TM) Pressure Monitoring System. Spinal Specialties markets its products to anesthesiologists and interventional radiologists through an in-house telemarketing team and a network of distributors.

Our revenues for the period were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Product Revenue:				
Neuromonitoring products	\$11,679	\$9,725	\$32,763	\$28,763
Operating room products	13,555	10,195	38,976	31,746
Instruments	13,141	3,517	31,746	16,349
Private label products	5,092	5,794	16,349	11,834
Total Product Revenue	43,467	29,231	119,834	88,692
Other revenue	3,591	973	6,740	1,500
Total Revenue	\$47,058	\$30,204	\$126,574	\$90,192

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) Dural Graft Matrix and NeuraGen(TM) Nerve Guide products and sales of neurosurgical shunt products acquired in 2002 accounted for the increase in operating room product revenues. Sales of the recently acquired JARIT(R) and Padgett(TM) surgical instrument lines contributed \$8.8 million of the year-over-year increase in instrument revenues. Increased sales of our ultrasonic aspirator products contributed the remainder of the growth in instrument product revenues. The decline in our private label product revenues is primarily attributable to a decline in revenues from the Absorbable Collagen Sponge we supply for use in Medtronic's INFUSE bone graft product.

Acquisitions and new product launches contributed significantly to our product revenue growth. Revenues from product lines acquired since the beginning of the third quarter of 2002 accounted for \$10.3 million of the increase in product revenues. Excluding revenues attributable to private label product lines, product lines acquired since the beginning of the third quarter of 2002, and the effect of changes in foreign currency exchange rates, third quarter 2003 product revenues increased by \$4.2 million, or 19%, over the prior year period. Excluding recently acquired product lines and changes in foreign currency exchange rates, third quarter 2003 product revenues increased by \$3.6 million, or 13%, over the prior year period, notwithstanding the decline in private label product revenues.

Gross margin on product revenues in the third quarter of 2003 was 57%. Our gross margin was negatively affected by the change in our product mix caused by recent acquisitions and by \$401,000 of inventory fair value purchase accounting adjustments from the sale of acquired JARIT inventory during the quarter. Excluding inventory fair value purchase accounting adjustments, our gross margin on product revenues would have been 58%.

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Research and development expense decreased \$2.1 million in the third quarter of 2003 primarily as a result of in-process research and development charges taken in the third quarter of 2002 in connection with the acquisitions of Signature Technologies, Inc. and of certain assets of Novus Monitoring Limited. Sales and marketing expense increased by \$3.4 million to \$10.1 million in the third quarter of 2003, and was 23% of product revenues in both the third quarter of 2003 and the prior year period. General and administrative expense decreased \$400,000 in the third quarter of 2003 to \$3.8 million.

We reported net interest expense of \$188,000 in the third quarter of 2003, as compared to net interest income of \$822,000 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 earlier this year. Other income increased by \$320,000 to \$309,000 as a result of gains realized on the sale of marketable securities and gains recorded in connection with an interest rate swap transaction executed in August. The interest rate swap has been designated as a hedge against changes in the fair value of our fixed-rate convertible debt.

The \$3.4 million increase in income tax expense in the third quarter of 2003 reflects an increase in our expected effective tax rate to 37.2% for 2003 as compared to 35% reported for the third quarter of 2002. This increase results primarily from a change in the geographic mix of projected taxable income for 2003, including the effects of the additional revenue associated with the amendment to our distribution agreement with ETHICON Inc.

The Company generated \$8.1 million in cash flows from operations in the third quarter of 2003. Year-to-date, we have generated \$31.2 million of operating cash flows in 2003, as compared to \$20.5 million in the prior year period.

The Company's cash and investments totaled \$209.1 million at September 30, 2003.

Integra is updating its expectations for product revenues and earnings for the remainder of 2003 and 2004. Our guidance for the fourth quarter of 2003 is for product revenues of \$45.5 to \$46.5 million. We expect to book additional other revenues, expenses and other income in connection with and as a result of the amendment to the ETHICON Inc. distribution agreement. Earnings per share for the fourth quarter of 2003 are expected to be in the range of \$0.28 to \$0.33.

We expect total revenues to increase to between \$205 million and \$215 million in 2004. Gross margin is expected to be 62% of product revenues in 2004. Excluding 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, we expect our earnings to be within a range of \$1.08 to \$1.14 per share in 2004. Management's expectations for 2003 and 2004 financial performance include the impact of the Spinal Specialties acquisition, as we expect the transaction to close in the next several days, but do not include the impact of acquisitions or other strategic corporate transactions that have not yet been announced.

We have scheduled a conference call for 9:00 am EST today, October 31, 2003, to discuss the financial results for the third 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) 935-2100 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 November 14, 2003 by dialing (973) 341-3080 (access code 3609053) or through the webcast accessible on our home page.

Integra LifeSciences Holdings Corporation is a diversified medical technology

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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 manufacturing and research facilities located throughout the world. We have approximately 850 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, income tax rates, earnings per share and cash flows 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 may adversely affect our future gross margins; the geographic mix of our taxable income may adversely affect our income tax rates; our ability to integrate acquired businesses, increase product sales and gross margins, and control non-product costs may affect our earnings per share; our future net income results and our ability to effectively manage working capital may affect our future cash flows; and our ability to complete required pre-closing conditions may affect our ability to close the Spinal Specialties acquisition. 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, recently acquired product lines, and changes in foreign currency exchange rates", "growth in product revenues excluding recently acquired product lines and changes in foreign currency exchange rates", and "gross margin on product revenues excluding inventory fair value purchase accounting adjustments", all of which are non-GAAP financial measures. A reconciliation of these non-GAAP financial measures to the most comparable GAAP measure is provided in the tables of financial information contained at the end of this news release.

These non-GAAP financial measures should not be relied upon to the exclusion of GAAP financial measures. Management believes that these non-GAAP financial measures are important supplemental information to investors which reflect 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.

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INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONSOLIDATED FINANCIAL RESULTS
(In thousands, except per share data)
(UNAUDITED)

Statement of Operations Data:

	Three Months Ended September 30,		
	2003	2002	
Product revenue	\$43,467	\$29,231	\$11
Other revenue	3,591	973	
Total revenue	47,058	30,204	1
Cost of product revenue	18,870	12,611	
Research and development	2,616	4,667	
Sales and marketing	10,090	6,720	
General and administrative	3,787	4,189	
Amortization	773	425	
Total costs and expenses	36,136	28,612	
Operating income	10,922	1,592	
Interest (expense) income, net	(188)	822	
Other income (expense), net	309	(11)	
Income before income taxes	11,043	2,403	
Provision for income taxes	4,210	840	1
Net income	\$6,833	\$1,563	\$
Diluted earnings per share	\$0.23	\$0.05	
Diluted weighted average common shares outstanding	30,286	30,654	

Condensed Balance Sheet Data:

	September 30, 2003	December 31, 2002
Cash and marketable securities, Including non-current portion	\$ 209,070	\$ 132,311
Accounts receivable, net	26,961	19,412
Inventory, net	38,395	28,502
Total assets	402,529	274,668
Current liabilities	32,443	21,921
Long-term debt	119,911	-
Total liabilities	155,474	27,071
Stockholders' equity	247,055	247,597

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

A. Growth in product revenues excluding private label products, recently acquired product lines, and changes in foreign currency exchange rates

Excluding revenues attributable to private label product lines, product lines acquired since the beginning of the third quarter of 2002 and the effect of changes in foreign currency exchange rates, third quarter 2003 product revenues increased by \$4.2 million, or 19%, over the prior year period.

	Quarter Ended September 30,		Increase (Decrease)	
	2003	2002	\$	%
	-----	-----	-----	-----
	(\$ in thousands)			
Total product revenues, as reported	\$ 43,467	\$ 29,231	\$14,236	49%
Less: Product revenues acquired in 2003	7,719	--	7,719	N/A
Product revenues acquired in 2002	5,124	2,533	2,591	102%
Impact of changes in foreign currency exchange rates	362	--	362	N/A
Private label product revenues(1)	4,419	5,062	(643)	(13%)
	-----	-----	-----	-----
Product revenues excluding acquired products, changes in foreign currency exchange rates and private label products	\$ 25,843	\$ 21,636	\$ 4,207	19%

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

B. Growth in product revenues excluding recently acquired product lines and changes in foreign currency exchange rates

Excluding recently acquired product lines and changes in foreign currency exchange rates, third quarter 2003 product revenues increased by \$3.6 million, or 13%, over the prior year period, notwithstanding the decline in private label product revenues.

	Quarter Ended September 30,		Increase (Decrease)	
	2003	2002	\$	%
	-----	-----	-----	-----
	(\$ in thousands)			
Total product revenues, as reported	\$ 43,467	\$ 29,231	\$14,236	49%
Less: Product revenues acquired in 2003	7,719	--	7,719	N/A
Product revenues acquired in 2002	5,124	2,533	2,591	102%
Impact of changes in foreign currency exchange rates	362	--	362	N/A
	-----	-----	-----	-----
Product revenues excluding acquired products and changes in foreign currency exchange rates	\$ 30,262	\$ 26,698	\$ 3,564	13%

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C. Gross margin on product revenues excluding inventory fair value purchase accounting adjustments

Excluding inventory fair value purchase accounting adjustments, our gross margin on product revenues would have been 58%.

	Three Months Ended September 30, 2003 ----- (\$ in thousands)
Total cost of product revenues, as reported	\$ 18,870
Less: Inventory fair value purchase accounting adjustments	401

Total cost of product revenues excluding inventory fair value purchase accounting adjustments	\$ 18,469
 Total product revenues, as reported	 \$ 43,467
Less: Total cost of product revenues, as reported	18,870

Gross margin on product revenues, as reported	24,597
Gross margin as % of product revenues, as reported	57%
 Total product revenues, as reported	 \$ 43,467
Less: Total cost of product revenues excluding inventory fair value purchase accounting adjustments	18,469

Gross margin on product revenues, adjusted to exclude inventory fair value purchase accounting adjustments	24,998
Gross margin as % of product revenues, adjusted to exclude inventory fair value purchase accounting adjustments	58%

Source: Integra LifeSciences Holdings Corporation