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INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
October 06, 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): September 30, 2003

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 5. Other Events.

On September 30, 2003, Integra LifeSciences Corporation and Ethicon, Inc., a division of Johnson & Johnson, ("Ethicon") entered into an amendment to their June 3, 1999 Supply, Distribution and Collaboration Agreement, which governs the marketing and distribution rights to INTEGRA Dermal Regeneration Template(R). Under the terms of the amendment, Ethicon's exclusive right to sell and market INTEGRA Dermal Regeneration Template will terminate on December 31, 2003 and Ethicon will make certain payments to Integra upon execution of the amendment and on December 31, 2003. Ethicon will continue to sell and market INTEGRA Dermal Regeneration Template through the end of this year under the terms of the 1999 agreement. On January 1, 2004 Integra LifeSciences Corporation will resume exclusive responsibility for the sales, marketing and distribution of the product.

ITEM 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(a) Not applicable

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(b) Not applicable

(c) Exhibits.

| Exhibit Number ----- | Description of Exhibit ----- |
|----------------------------|---|
| 10.1 | Amendment to Supply, Distribution and Collaboration Agreement by and between Integra LifeSciences Corporation and Ethicon, Inc. dated as of September 30, 2003. |
| 99.1 | Press release issued October 6, 2003 regarding amendment to the INTEGRA Dermal Regeneration Template Supply, Distribution and Collaboration Agreement.* |
| | *This exhibit is being furnished under Item 5, Other Events 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: October 6, 2003

By: /s/ Stuart M. Essig

Stuart M. Essig

President and Chief Executive Officer

Exhibit Index

| Exhibit Number ----- | Description of Exhibit ----- |
|----------------------------|---|
| 10.1 | Amendment to Supply, Distribution and Collaboration Agreement |

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99.1 by and between Integra LifeSciences Corporation and Ethicon, Inc. dated as of September 30, 2003. Press release issued October 6, 2003 regarding amendment to the INTEGRA Dermal Regeneration Template Supply, Distribution and Collaboration Agreement.

Exhibit 10.1

Amendment to Supply, Distribution and Collaboration Agreement

This Amendment to Supply, Distribution and Collaboration Agreement (this "Amendment") is effective as of September 30, 2003 by and between Integra LifeSciences Corporation, a Delaware corporation ("Integra") and Ethicon, Inc., a New Jersey corporation ("Ethicon") on behalf of its Johnson & Johnson Wound Management(TM) division.

WHEREAS, Integra and the Johnson & Johnson Medical division of Ethicon, Inc. ("JJM") entered into a Supply, Distribution and Collaboration Agreement, dated June 3, 1999 relating to the Integra(TM) Dermal Regeneration Template(TM) (the "Original Agreement"); and

WHEREAS, Johnson & Johnson Wound Management(TM) ("JJWM") is the division of Ethicon which is the successor through reorganization of Johnson & Johnson Medical(TM) ; and

WHEREAS, Integra and JJWM deem it in their mutual interests to amend the Original Agreement in the manner described below.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the parties hereto, intending to be legally bound, hereby agree as follows:

1. General. The purpose of this Amendment is to amend certain specific provisions of the Original Agreement. All capitalized terms used but not defined herein are used as defined in the Original Agreement. Except as expressly modified by this Amendment, all terms and conditions of the Original Agreement shall remain in full force and effect. The Original Agreement as amended by this Amendment is referred to as the "Agreement."

2. Replacement of References to JJM. All references to JJM in the Original Agreement are hereby amended to be references to JJWM.

3. Adjustment of Termination Date; Orderly Transition.

(a) Section 29.1 of the Agreement is hereby amended in its entirety to read as follows:

Section 29.1 Term. The term of this Agreement shall commence on the date hereof and shall expire on December 31, 2003. For purposes of this Agreement, such period shall be referred to as both the "Initial Period" and the "Term". JJWM shall have no right to extend the Term of this Agreement and any references herein to "Extension Periods" shall be of

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no force or effect.

(b) During the period between the date of this Amendment and the expiration of the Term of the Agreement, except as otherwise expressly provided for in this Amendment, the provisions of the Agreement shall remain in full force and effect, JJWM shall continue to use its commercially reasonable efforts to market and sell the Products in the Territory and JJWM shall not enter into any transactions or take any actions with respect to the Products other than in the ordinary course of business consistent with its past practices, and Integra shall continue to meet JJWM's purchase orders consistent with its past practices.

(c) During the period between the date of this Amendment and the expiration of the Term of the Agreement, the Joint Steering Committee shall meet at intervals no less frequent than once every two weeks to plan for and coordinate an orderly transition from JJWM to Integra of the marketing, sales, distribution, order processing, billing and collection, intellectual property, domestic and international complaints management, regulatory matters, clinical matters and research and development, in each case relating to the Products throughout the Territory, and JJWM shall use all commercially reasonable efforts to effect such transition at its expense prior to January 1, 2004 (except for those elements of the transition that the parties agree shall occur after such date). Such transition plan (the "Transition Plan") shall include, among other things, the elements specified in Exhibit A to this Amendment (the "Transition Plan Requirements").

(d) During the period between the date of this Amendment and the expiration of the Term of the Agreement, Integra agrees to refrain from direct contact with any of JJWM's customers of Product relating to the marketing and/or sales of such Product without the prior written consent of JJWM. Notwithstanding the preceding sentence, JJWM will work with Integra on developing and implementing a plan where joint customer visits will be initiated in December 2003.

(e) From and after the date of this Amendment, the provisions of Sections 2.3 and 2.4 shall cease to apply and shall be of no further force and effect; JJWM shall be relieved of its obligation under Section 3.3 to deliver a marketing plan for the calendar year 2004, and Integra shall be relieved of its obligation under Section 11.3 to deliver an annual research plan for the calendar year 2004. In addition, notwithstanding the provisions of Section 4(a), JJWM shall have no obligation to purchase forecasted quantities of Products for any time period after December 31, 2003.

4. C&R Event Payments.

(a) JJWM hereby acknowledges the C&R Event set forth in Section 13.1(vi) of the Original Agreement to have been achieved and, simultaneously with the execution and delivery of this Amendment, JJWM shall pay Integra \$500,000 in respect thereof.

(b) Simultaneously with the execution and delivery of this Amendment, JJWM shall pay Integra \$2,000,000 for the completion of the C&R Events that were described in the C&R

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Notice dated January 31, 2003 previously submitted to JJWM.

(c) In consideration for the payments above, Integra and JJWM agree that no additional C&R Event Payments will be due and owing from JJWM to Integra under the Agreement, and Integra hereby waives any claims which it has had or may have with respect to the payment of such C&R Event Payments.

5. Effect of Termination. Upon the expiration of the Agreement at the end of the Term, in addition to the provisions of the Agreement contained in Section 29.3:

(a) JJWM shall pay to Integra on December 31, 2003 by wire transfer \$2,000,000; provided that during the period between the execution of this Amendment and the expiration of the Term, if any JJWM customer orders have not been filled because of action or inaction by Integra, such \$2,000,000 payment will be reduced by an amount equal to (A) the customer purchase prices of such unfilled orders times (B) 62.5%.

(b) JJWM and its affiliates shall cooperate fully in the completion of those elements of the Transition Plan that have not been completed by December 31, 2003, until such elements have been completed;

(c) JJWM shall assign or transfer to Integra any assets (whether tangible or intangible) to be transferred to Integra pursuant to the Transition Plan;

(d) JJWM shall assign the "Avagen" trademark to Integra;

(e) Notwithstanding Section 29.3(v), the license to reproduce the Licensed Trademark granted by Integra to JJWM pursuant to Section 5.2 of the Original Agreement shall terminate on December 31, 2003;

(f) Notwithstanding Sections 29.3(vi - viii), any rights and interests to Jointly-Owned Inventions in the Field owned by JJWM or its affiliates shall be assigned to Integra on December 31, 2003, and such Jointly-Owned Inventions thereafter shall be the property of Integra exclusively.

6. Final Payments Obligations. Integra acknowledges that the following quarterly payments made or to be made by JJWM to Integra for the fourth quarter 2003: (1) the \$500,000 quarterly Research Payment pursuant to Section 12.1 (to be made on or around October 1, 2003) and (2) the \$2,109,375 quarterly Minimum Prepayment pursuant to Sections 6.7 and 6.8, shall represent JJWM's final payment obligations to Integra under those sections in the Agreement prior to the end of the Term. Integra further acknowledges that JJWM's payments to Integra under paragraphs 4(a), 4(b), 5(a) and 6 of this Amendment shall represent JJWM's final payment obligations to Integra under the Agreement and this Amendment, with the exception of those specific costs for which JJWM will be responsible for relating to transition services in Exhibit A.

7. Release. Effective upon the execution of this Amendment, the parties for themselves and their successors and assigns, hereby release and forever discharge each other, and each other's officers, directors, employees, agents, representatives, contract manufacturers, and licensees, from any and all claims, demands, and causes of action whatsoever, known or unknown, that either party may have arising out of the Original Agreement and Amendments prior to and as of the date hereof.

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8. Further Assurances. Each of the parties shall execute, prior to and following December 31, 2003, such documents and other papers and perform such further acts as may be reasonably required or desirable to carry out the provisions hereof and the transactions contemplated hereby, including with respect to the transactions contemplated by the Transition Plan.

9. Counterparts. This Amendment may be executed and delivered (including by facsimile transmission) in one or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of this 30th day of September, 2003.

INTEGRA LIFESCIENCES CORPORATION

By: _____

Name:
Title:

JOHNSON & JOHNSON WOUND MANAGEMENT,
A DIVISION OF ETHICON, INC.

By: _____

Name:
Title:

Exhibit 99.1

News Release

Contacts:

Integra LifeSciences Holdings Corporation
John B. Henneman, III
Executive Vice President
Chief Administrative Officer

John Bostjancic
Senior Director of Finance
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Integra LifeSciences Announces Plans to Market
INTEGRA Dermal Regeneration Template(R) through its Direct Sales Force

Alliance with ETHICON, Inc. to Terminate at end of 2003

Plainsboro, NJ / October 6, 2003 / -- Integra LifeSciences Holdings Corporation (NASDAQ: IART - news) announced today that it has reached agreement with ETHICON Inc. for the return to Integra of the exclusive right to sell, market and distribute the INTEGRA Dermal Regeneration Template(R).

The INTEGRA Dermal Regeneration Template is the first and only product to receive FDA approval as a skin replacement system with a claim for regeneration of dermal tissue for the treatment of life-threatening burns and repair of scar contractures. INTEGRA Dermal Regeneration Template was developed by Integra LifeSciences Corporation, and has been sold in the United States since 1996. In that time, the INTEGRA product has helped thousands of patients recover from severe thermal injuries.

ETHICON will continue to sell and market the product through the end of this year under the terms of a 1999 supply and distribution agreement between Integra and ETHICON. In 2004 Integra LifeSciences Corporation will resume exclusive responsibility for the sales, marketing and distribution of the product. Integra and ETHICON are working together to develop a plan to ensure a smooth transition of the product's distribution.

"We are delighted to again take responsibility for the sales, marketing and clinical education for this extraordinary product," said Stuart M. Essig, Integra's President and Chief Executive Officer. "In the four years that ETHICON has managed the INTEGRA product, it has attained widespread use in burn units for the treatment of life threatening burns. Going forward, our objective will be to continue to expand the usage of INTEGRA Dermal Regeneration Template to the plastic and reconstructive markets."

Integra expects the impact of the amendment to be accretive to earnings in 2003 and neutral or accretive to earnings in 2004. Certain amounts, including event payment revenues related to the prior achievement of clinical and regulatory events, and various revenues, transition costs and other income amounts related to the amendment, will be recognized during the third and fourth quarters of 2003. Additional financial information will be made available on Integra LifeSciences' quarterly earnings conference call, which is scheduled for October 31, 2003 at 9:00 a.m.

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 soft tissue repair. Integra is a leader in applying the principles of biotechnology to medical devices that improve patients' quality of life. The Company has its corporate headquarters in Plainsboro, New Jersey, with manufacturing and research facilities located throughout the world. The Company has approximately 860 permanent employees. Please visit the Company's 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 expectations for Integra's ability to expand the usage of the INTEGRA product to the plastic and reconstructive markets and the impact that the amendment to the supply and

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distribution agreement will have on Integra's future financial results. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results. Among other things, Integra LifeSciences Corporation's ability to successfully recruit and build a direct sales and marketing infrastructure around the INTEGRA product may affect its ability to expand the usage of the product to the plastic and reconstructive markets, and the costs of maintaining such a direct sales and marketing infrastructure may affect Integra LifeSciences Corporation's future financial results. 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.

Source: Integra LifeSciences Holdings Corporation