INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
November 13, 2012

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 13, 2012

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)

Registrant s telephone number, including area code: (609) 275-0500

Not Applicable

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 7.01 REGULATION FD DISCLOSURE

Attached as Exhibit 99.1 and incorporated into this Item 7.01 by reference is the warning letter, dated November 1, 2012, from the United States Food and Drug Administration (the FDA) to Integra NeuroSciences Ltd., a wholly-owned indirect subsidiary of Integra LifeSciences Holdings Corporation (the Company). The warning letter related to quality systems issues at its manufacturing facility located in Andover, England. The letter, which was received on November 5, 2012, resulted from an inspection held at that facility in June 2012.

The warning letter does not restrict the Company s ability to manufacture or ship products or import them in to the United States. It also does it require the recall of products. The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis and, since the conclusion of the inspection, has undertaken significant efforts to remediate the observations.

The Andover facility manufactures components of the CUSA ultrasonic aspirator system, and intracranial pressure monitors. Sales of products manufactured in the Andover facility constituted less than 3% of the Company s consolidated revenues in the twelve months ended September 30, 2012. The Company does not expect to incur material incremental expense in the fourth quarter of 2012 on remediation activities.

The Company disclosed the warning letter in a press release issued concurrently with the filing of this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K is being furnished and shall not be deemed filed for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section. The information contained in Item 7.01 of this Current Report on Form 8-K shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Letter dated November 1, 2012 from the United States Food and Drug Administration to Integra NeuroSciences Ltd.

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 13, 2012

By: /s/ John B. Henneman, III
John B. Henneman, III
Title: Executive Vice President,
Finance and Administration,
and Chief Financial Officer

Exhibit Index

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