INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
February 19, 2013

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 14, 2013

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

On February 14, 2013, Integra LifeSciences Corporation, a wholly-owned subsidiary of Integra LifeSciences Holdings Corporation (the Company) received a warning letter, dated February 13, 2013, from the United States Food and Drug Administration (the FDA). A copy of the warning letter redacted to remove confidential information is attached as Exhibit 99.1 and incorporated to this Item 7.01 by reference. The Company submitted a request for confidential treatment with the United States Securities and Exchange Commission (the Commission) in connection with the omitted portions of the letter.

The warning letter relates to quality systems issues at its manufacturing facility located in Añasco, Puerto Rico. The letter resulted from an inspection conducted at that facility during October and November 2012.

The Añasco facility manufactures and finishes products that accounted for approximately 18% of the Company s consolidated revenues in 2012. Those products include many of the Company s regenerative medicine collagen products, including Duragen® Dural Graft Matrix. The Company has the capability to produce most of the relevant products in its Plainsboro, New Jersey facility.

The warning letter cites concerns relating to process validations, corrective and preventative actions (CAPA), and document controls. It includes, among other things, a request that the Company prevent the distribution of collagen products manufactured at [the] Añasco site that do not have successful and complete validation studies. On February 15, the Company stopped distribution of its collagen products manufactured in the Añasco facility in order to confirm that it had successfully validated all such products, and engaged a third-party consultant having appropriate quality system regulations (QSR) expertise to confirm such validations. In the Company s opinion, it has successfully completed all such validations, and it expects that the third-party consultant will certify the completeness of such validations by February 26, 2013, after which the Company will resume distribution of such products.

The Company has reviewed the complaint history of the affected products, and there is no indication that any distributed products pose a risk to patients.

The FDA s inspectional findings related to process validations and CAPAs that describe events in 2009, 2010, and 2011. In the fourth quarter of 2011, the Company initiated a comprehensive review and remediation of the quality systems and processes in the Añasco facility. That review and remediation uncovered the issues addressed in the warning letter and included the initiation of CAPAs designed to remediate those issues. The Company had already completed most of the work under those CAPAs by the time of the FDA s inspection in October 2012, and as of this week has completed substantially all such work. Accordingly, the Company does not expect materially higher expenses in 2013 to complete its remediation of the Añasco facility.

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

The Company takes this matter seriously. Any further actions by the FDA could have a material adverse impact on our financial position and operating results. The Company intends to implement corrective actions to address the concerns identified in the warning letter. The Company cannot, however, give any assurances that the FDA will be satisfied with its response to the warning letter or as to the expected date of the resolution of the matters included in the warning letter. Until the violations are corrected, the Company may be subject to additional regulatory action by the FDA, including seizure, injunction and/or civil money penalties. Additionally, requests for Certificates to Foreign Governments related to products manufactured at the Añasco facility will not be granted and premarket approval applications for Class III devices to which the QSR deviations are reasonably related will not be approved until the violations have been corrected. The Company presently has no such applications before the FDA.

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.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

99.1 * Letter, dated February 13, 2013, from the United States Federal Drug Administration to Integra LifeSciences Corporation

* Application has been made to the Commission for confidential treatment of certain provisions of this exhibit. Omitted information for which confidential treatment has been requested has been filed separately with the Commission.

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 19, 2013

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

EXHIBIT INDEX

Exhibit No.	Description
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