INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
January 05, 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): January 5, 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 December 21, 2011, from the United States Food and Drug Administration (the FDA) to Integra LifeSciences Corporation, a wholly-owned subsidiary of Integra LifeSciences Holdings Corporation (the Company). The warning letter related to quality systems and compliance issues at its collagen manufacturing facility located in Plainsboro, New Jersey. The letter resulted from an inspection held at that facility in August 2011, and did not identify any new observations that were not provided in the Form 483 that followed the inspection.

The warning letter does not restrict the Company s ability to manufacture or ship products. Nor does it require the recall of any product. The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis. The Company expects to remain on track with these actions and to continue to work expeditiously to address all of the issues that the FDA identified

Since the conclusion of the inspection in late August, 2011, the Company has undertaken significant efforts to remediate the observations that the FDA has made and continues to do so. The Company completed construction activities at the facility and all clean rooms were in production at the end of 2011.

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.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.
(d) Exhibits

99.1 Letter, dated December 21, 2011, from the United States Federal Drug Administration to Integra LifeSciences Corporation

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: January 5, 2012

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Letter, dated December 21, 2011, from the United States Federal Drug Administration to Integra LifeSciences Corporation