INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
December 03, 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): November 26, 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 8.01 Other Events.**

On November 26, 2013, the United States Food and Drug Administration (the FDA ) completed an inspection of the regenerative medicine facility in Añasco, Puerto Rico (the Añasco Facility ) of Integra LifeSciences Corporation, a wholly-owned subsidiary of Integra LifeSciences Holdings Corporation (the Company ). The Añasco Facility is operating subject to an FDA warning letter dated February 13, 2013 (the Warning Letter ) that relates to quality systems and compliance issues. The inspection began on October 25, 2013 and focused primarily on the issues raised in the Warning Letter. At the end of the inspection, the FDA issued a new Form 483 with six observations, relating to Corrective and Preventative Action ( CAPA ), quality system procedures and instructions, procedures pertaining to complaints, procedures pertaining to checking and maintaining equipment, procedures for finished device acceptance and procedures to prevent contamination of equipment or products. Of these, the FDA designated the first observation, related to CAPA, and the third observation, related to complaint procedures, as repeat observations. The FDA did not issue repeat observations about validated processes, document control procedures, process control procedures or schedules for the adjustment, cleaning and maintenance of equipment The Company had committed to several corporate-wide corrections and additional site corrections and will continue to complete these within the timeframes provided to the FDA in order remediate the observations that the FDA has made. A copy of the FDA Form 483 is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| | |
|---|---|
| 99.1* | Food and Drug Administration Form FDA-483, dated November 26, 2013, relating to the inspection of the Añasco Facility |

* 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: December 3, 2013

By: /s/ Peter J. Arduini
Peter J. Arduini
Title: President and Chief Executive Officer

**EXHIBIT INDEX**

| Exhibit Number | Exhibit |
|---|---|
| 99.1* | Food and Drug Administration Form FDA-483, dated November 26, 2013, relating to the inspection of the Añasco Facility |

* 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.