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): March 7, 2019

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 8.01 OTHER EVENTS.

On March 7, 2019, a subsidiary of Integra LifeSciences Holdings Corporation (the "Company") received a warning letter, dated March 6, 2019, from the United States Food and Drug Administration (the "FDA").

The warning letter relates to quality systems issues at our manufacturing facility located in Boston, Massachusetts. The letter resulted from an inspection held at that facility in October and November 2018, and did not identify any new observations that were not already provided in the Form 483 that followed the inspection. We take the matters identified in the letter seriously and are in the process of preparing a written response to the letter. 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 and continues to do so.

The warning letter does not restrict the Company's ability to manufacture or ship products or require the recall of any products. Nor does it restrict our ability to seek FDA 510(k) clearance of products. The letter states that requests for Certificates to Foreign Governments will not be granted until the violations have been corrected. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected.

The Boston facility manufactures extracellular bovine matrix (EBM) products. Sales of products manufactured in the Boston facility constituted less than 4% of the Company's consolidated revenues in the twelve months ended December 31, 2018. The Company does not expect to incur material incremental expense for remediation activities. We cannot, however, give any assurances that the FDA will be satisfied with our response to the letter or as to the expected date of the resolution of the matters included in the letter. Until the issues cited in the letter are resolved to the FDA's satisfaction, the FDA may initiate additional regulatory action without further notice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products and could have a material adverse effect on our business, financial condition and results of operations.

Cautionary Statement Regarding Forward-Looking Statements

This report includes forward-looking statements within the meaning of federal securities laws. Forward-looking statements may be identified by the fact that they do not relate strictly to historical or current facts. They often include words such as "believe," "may," "could," "will," "expect," "continue," "anticipate," "intend," "estimate," "plan" and similar expressions. These forward-looking statements are based on current beliefs, expectations and assumptions that are subject to significant risks, uncertainties and changes in circumstances that could cause actual results to differ materially from the forward-looking statements. These risks, uncertainties and changes in circumstances include, but are not limited to, the success of our quality initiatives; our ability to remediate matters identified in inspectional observations or warning letters issued by the FDA, while continuing to satisfy the demand for our products; and challenges relating to changes in and compliance with governmental laws and regulations affecting our U.S. and international businesses, including regulations of the FDA and foreign government regulators, such as more stringent requirements for regulatory clearance of our products. Forward-looking statements contained in this report should be considered in light of these factors and those factors discussed from time to time in our periodic reports filed with the Securities and Exchange Commission, such as those discussed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018. Forward-looking statements speak only as of the date they are made and we expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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: March 11, 2019

By: /s/ Glenn G. Coleman
Glenn G. Coleman
Title: Corporate Vice President and Chief Financial Officer