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): **May 22, 2023**

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)	(IRS Employer Identification No.)

1100 Campus Road
Princeton, NJ 08540
(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 (see General Instruction A.2. below):

☐ 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)).

Securities Registered Pursuant to Section12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Exchange on Which Registered**
Common Stock, Par Value $.01 Per Share	IART	Nasdaq Global Select Market

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 2.06 Material Impairments

As more fully described in Item 7.01 of this Current Report on Form 8-K, Integra LifeSciences Holdings Corporation (the "Company"), after consultation with the U.S. Food and Drug Administration (the "FDA"), initiated a voluntary global recall of all products manufactured in its Boston, Massachusetts facility (the "Boston facility") distributed between March 1, 2018 and May 22, 2023 (the "voluntary recall").

As a result, the Company concluded on May 22, 2023 that it expects it will incur an impairment charge related to the write-off of inventories, net, of approximately $22 million. The Company expects this charge will be recorded in the quarter ending June 30, 2023. The Company does not expect this charge will result in any future cash expenditures.

ITEM 7.01 Regulation FD Disclosure

The Company identified through an internal investigation process in its Boston facility deviations with endotoxin testing that may have resulted in the release of products with higher levels of endotoxins than permitted by the product specifications. Higher levels of endotoxins can induce an immune response, leading to a post-operative fever. Although there is no specific indication of any reported product complaints related to high endotoxin levels, the Company, in accordance with its commitment to patient safety and product quality, has decided to initiate the voluntary recall and extend the temporary halt of manufacturing at its Boston facility to implement additional detection and quality controls. The Company expects to resume manufacturing at its Boston facility following implementation of such controls.

The voluntary recall includes the SurgiMend®, PriMatrix®, Revize™ and TissueMend™ products.

The Company expects that the voluntary recall and manufacturing stoppage will have the greatest impact on the Tissue Technologies segment, including Private Label, and has revised guidance. For the second quarter, the Company expects reported revenues in the range of $372 million to $376 million and adjusted earnings per diluted share to be in the range of $0.55 to $0.59.

While it is difficult to estimate at this time the impact of the voluntary recall for the full year, if the manufacturing stoppage continued through the remainder of 2023, the Company estimates full-year revenue and adjusted earnings per share guidance provided during the Company's April earnings announcement would be negatively affected by approximately $60 million and $0.35, respectively. Products manufactured at the Boston facility represent approximately 5% of the Company's consolidated revenues. The Company expects to provide updated details on its full-year guidance during its second quarter 2023 financial results conference call.

Adjusted earnings per diluted share is a non-GAAP financial measure and is calculated by dividing adjusted net income attributable to diluted shares by diluted weighted average shares outstanding. The measure of adjusted net income consists of GAAP net income, excluding: (i) structural optimization charges; (ii) divestiture, acquisition and integration-related charges; (iii) EU Medical Device Regulation-related charges; (iv) intangible asset amortization expense; (v) certain expenses associated with the voluntary recall; and (vi) income tax impact from adjustments.

The Company believes that the presentation of adjusted earnings per diluted share measure provides important supplemental information to management and investors regarding financial and business trends relating to the Company's financial condition and results of operations. Management uses such non-GAAP financial measure when evaluating operating performance because we believe that the inclusion or exclusion of the items described below, for which the amounts and/or timing may vary significantly depending upon the Company's divestiture, acquisition, integration, and restructuring activities, for which the amounts are non-cash in nature, or for which the amounts are not expected to recur at the same magnitude, provides a supplemental measure of our operating results that facilitates comparability of our financial condition and operating performance from period to period, against our business model objectives, and against other companies in our industry. This measure should be considered in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

The Company provided the foregoing forward-looking guidance regarding adjusted earnings per diluted share but has not provided a reconciliation to GAAP earnings per share, because certain GAAP expense items are highly variable and management is unable to predict them with reasonable certainty and without unreasonable effort. Specifically, the financial impact and timing of divestitures, acquisitions, integrations, structural optimization, efforts to comply with the EU Medical Device Regulation and expenses associated with the voluntary recall are uncertain, depend on various dynamic factors and are not reasonably ascertainable at this time. These expense items could have a material impact on GAAP results. In addition, the Company believes such a reconciliation would imply a degree of precision and certainty that could be confusing to investors.

The information in this Item 7.01 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like “believe,” “expect,” “plan,” and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding the issues causing the voluntary removal of the Company’s products manufactured at its Boston facility, the potential effects of the process deviations identified at the Boston facility, the anticipated impact of the voluntary recall and manufacturing stoppage on the Company’s business, the Company’s ability to address in a timely manner the product-related issues discussed above and resume manufacturing activities at its Boston facility, and the Company’s future financial performance, including the expected amount and timing for recording charges associated with the recall. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ from predicted results. These risks and uncertainties include market conditions and other factors beyond the Company's control and the economic, competitive, governmental, technological and other factors identified under the heading "Risk Factors" included in item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, and information contained in subsequent filings with the Securities and Exchange Commission. These forward-looking statements are made only as the date thereof, and the Company undertakes no obligation to update or revise the 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: May 23, 2023

By: /s/ Eric I. Schwartz
Eric I. Schwartz
Title: Executive Vice President, Chief Legal Officer and Secretary