

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): August 18, 2022

**INTEGRA LIFESCIENCES HOLDINGS
CORPORATION**

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
Of Incorporation)

0-26224
(Commission
File Number)

51-0317849
(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 Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of Each 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 7.01 REGULATION FD DISCLOSURE

On August 18, 2022, Integra LifeSciences Holdings Corporation (the “Company”), after consultation with the U.S. Food and Drug Administration and other regulatory authorities outside of the United States, initiated an immediate voluntary global product removal of all CereLink® intracranial pressure monitors as a result of customer reports about monitors whose pressure readings were out of range. The Company believes that the out-of-range readings are principally caused by electrical interference from the external environment and/or interference from a component on the circuit board of the monitor. These out-of-range readings have occurred at a low incidence rate and at a limited number of sites; however, out of an abundance of caution, the Company has decided to remove all CereLink monitors from the field.

The Company is continuing its investigation into the matter in order to remedy the observed issue and plans to resume shipment of the CereLink monitors as soon as any such issues have been resolved.

The Company does not currently expect that this voluntary action will have a material adverse effect on the Company’s business, financial condition or results of operations. Nevertheless, as a result of the voluntary action, the Company estimates a returns provision of approximately \$9 million in the third quarter of 2022 and has adjusted its third quarter and full year 2022 guidance accordingly. Updated guidance estimates are shown below.

	Revenue (\$ millions)		Adj. EPS (\$)	
	Low	High	Low	High
Third Quarter				
July guidance	383	391	0.78	0.82
Cerelink returns provision estimate	(9)	(9)	(0.09)	(0.09)
Updated guidance	374	382	0.69	0.73
Full Year				
July guidance	1,557	1,575	3.21	3.29
Cerelink returns provision estimate	(9)	(9)	(0.09)	(0.09)
Updated guidance	1,548	1,566	3.12	3.20

The adjusted earnings per diluted share measure 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; and (v) 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 and efforts to comply with the EU Medical Device Regulation 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.

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 CereLink® intracranial pressure monitoring system, the Company’s efforts to resolve any such issues and resume shipment of the CereLink monitoring system, and the Company’s future financial performance. 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, 2021, 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: August 24, 2022

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