HOLOGIC INC
Form 8-K
September 12, 2018

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) September 12, 2018

HOLOGIC, INC.
(Exact Name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction of Incorporation)

1-36214	04-2902449
(Commission File Number)	(I.R.S. Employer Identification No.)

250 Campus Drive, Marlborough, MA	01752
(Address of Principal Executive Offices)	(Zip Code)

(508) 263-2900
(Registrant's Telephone Number, Including Area Code)

(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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
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 August 13, 2018, Hologic, Inc. (the "Company") issued a Form 8-K describing the decision by its Cynosure division to suspend marketing and distribution of its TempSure™ Vitalia handpieces and single-use probes, and to ask customers to return any Vitalia handpieces and unused probes they had purchased. Cynosure had launched the Vitalia handpiece and probe under an FDA 510(k) clearance and had been marketing the device for heating of vaginal tissue.

This decision was made in response to a public statement made by the FDA and letters it sent to Cynosure and other medical aesthetics companies expressing concerns regarding "vaginal rejuvenation" procedures using energy-based devices. Cynosure received such a letter relating to its MonaLisa Touch® laser.

The Company is now providing an update on the financial impact of its actions in advance of meetings with investors at the Morgan Stanley 16th Annual Global Healthcare Conference later this week.

Based on discussions with medical aesthetics customers over the last month, and relative to its financial guidance provided on July 31, 2018, the Company now expects Cynosure revenue in the current fourth quarter of fiscal 2018 to be approximately $15 million less than previously forecast. This estimate includes lost sales of TempSure Vitalia in the fourth quarter; refunds and rebates associated with prior sales of Vitalia handpieces, unused probes and TempSure systems; and reduced sales of MonaLisa Touch.

However, based on strong revenue trends in other parts of Hologic's business in the current quarter to date, the Company is reaffirming its financial guidance provided on July 31, 2018. Specifically, the Company continues to expect revenue in the fiscal fourth quarter to be in the range of $800 to $815 million. Since refunds and rebates related to TempSure Vitalia will be recorded as reductions to revenue, which reduce operating income on a dollar-for-dollar basis, the Company now expects earnings per share (EPS) in the fiscal fourth quarter to be at the low end of its previous GAAP and non-GAAP guidance ranges.

Hologic cannot yet predict when it will resume selling TempSure Vitalia. The Company is committed to marketing its products in compliance with FDA requirements and believes a higher level of scrutiny from regulatory authorities will benefit its customers and patients.

Cautionary Note Regarding Forward-Looking Statements. The information in this Form 8-K contains forward-looking statements that involve certain risks and uncertainties which could cause actual results to differ materially from those expressed or implied by these statements. Such risks and uncertainties include the number of customers who return product, the views of the FDA regarding product claims and other factors that are described in the filings made by the Company with the SEC, including our Annual Report on Form 10-K. The Company does not undertake to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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.

Date: September 12, 2018 HOLOGIC, INC.

By: /s/ Karleen M. Oberton
Karleen M. Oberton
Chief Financial Officer