HOLOGIC INC
Form 8-K
August 13, 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) August 13, 2018

HOLOGIC, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation)

1-36214	**04-2902449**
(Commission	**(I.R.S. Employer**

File Number) **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 July 30, 2018, the FDA issued a public statement and sent letters to a number of companies in the medical aesthetics industry expressing concerns regarding vaginal rejuvenation procedures using energy-based devices. As previously disclosed, Hologic, Inc. (the Company) and its division, Cynosure, received such a letter relating to the MonaLisa Touch® laser (the MLT Letter). As a leader in women s health, Hologic has a strong track record of developing products based on science and clinical evidence, as well as meeting our regulatory obligations. As such, we take the FDA s recent statements very seriously.

Cynosure recently launched the TempSure Vitalia handpiece and probe under an FDA 510(k) clearance and was marketing the device for heating of vaginal tissue. Although the FDA did not mention Vitalia in its recent comments or the MLT Letter, Cynosure has carefully considered the FDA s broader concerns and elected to suspend marketing and distribution of Vitalia handpieces and single-use probes until it has confirmed they meet all regulatory requirements for devices in this category. Cynosure is also asking customers to return any Vitalia handpieces and unused probes they have purchased. Cynosure has had no reports of adverse effects associated with the use of the Vitalia handpiece and probe and has not been made aware of any patient harm associated with their use. A letter describing these decisions is being sent to customers today.

This action is limited to the Vitalia probe and handpiece and does not affect other Hologic gynecology products such as the MonaLisa Touch laser. In addition, the TempSure System remains FDA-cleared and may continue to be used with its various other handpieces, including TempSure Envi.

The Company had previously forecast that revenue from TempSure Vitalia would be approximately $7 million in the fourth quarter of fiscal 2018. In addition, any returns of Vitalia handpieces, unused probes and TempSure systems are expected to be recorded as a reduction to revenue, primarily in the fourth quarter of fiscal 2018. Because the number of these returns is uncertain, Hologic is not able to accurately forecast the financial effect, including any potential impact on the full-year and fourth-quarter financial guidance provided on July 31, 2018, of these decisions at this time. Hologic is committed to marketing our products in compliance with FDA requirements and believes a higher level of scrutiny from regulatory authorities will benefit our customers and patients. We share the same goals as FDA clinically strong products that improve patient lives and are marketed responsibly.

Limitation on Incorporation by Reference. The information furnished in this Item 7.01 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 such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as set forth by specific reference in such a filing.

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: August 13, 2018

HOLOGIC, INC.

By: /s/ John M. Griffin
John M. Griffin

General Counsel