BAXTER INTERNATIONAL INC
Form 8-K
July 17, 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): July 17, 2018

Baxter International Inc.

(Exact name of registrant as specified in its charter)

Delaware	**1-4448**	**36-0781620**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

One Baxter Parkway, Deerfield, Illinois	**60015**
(Address of principal executive offices)	**(Zip Code)**

(224) 948-2000

(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 (§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 July 17, 2018, The U.S. Food and Drug Administration (FDA) released a copy of a Warning Letter (Claris Warning Letter) in connection with FDA s July 2017 inspection of the company s newly acquired facilities in Ahmedabad, India and the issuance of a related Form-483 (Claris 483). As previously disclosed by the company, FDA had commenced this inspection at the time of the closing of the company s acquisition of these facilities on July 27, 2017. The Claris Warning Letter is based on observations identified during that inspection.

We refer you to https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm613538.htm which contains a redacted copy of the Claris Warning Letter.

Prior to issuance of the Claris Warning Letter, the company had timely responded to the Claris 483. Additionally, the company has already implemented corrective actions to many of the issues raised in the Claris Warning Letter.

Coming out of the 2017 inspection, the company did not include any 2018 revenue for new Claris product launches in the U.S. in its 2018 financial guidance. Receipt of the Claris Warning Letter does not cause the company to make any changes to its Long Range financial guidance issued in May 2018 at this time. In addition, the company is evaluating other potential locations, including contract manufacturing organizations, to support the production of new products for distribution in the U.S., to mitigate the risk of any delay in its ability to fully remediate the Claris Injectables facilities to FDA s satisfaction beyond the first half of 2020. These other locations could also be used to support the production of any pending product approvals.

As set forth in the Claris Warning Letter, FDA has requested a Regulatory Meeting with the company. The company expects for that meeting to occur in 2018, with a reinspection of the former Claris Injectables facility to follow. While the company cannot guarantee the timing of any FDA inspection, the company expects for it to occur by the end of the first half of 2019.

The company will respond to the Claris Warning Letter in the time frame required by FDA.

This Form 8-K may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to statements regarding the potential impact of Claris Warning Letter on the company s Long Range guidance issued in May 2018, the approval of new products for distribution into the U.S. or the company s ability to implement (or the cost of implementing) corrective actions. Use of the words may, will, would, could, should, believes, estimates, projects, potential, expects, plans, seeks, intends, e anticipates, continues, designs, impacts, affects, forecasts, target, outlook, initiative, objective, c goal, or the negative of those words or other similar expressions is intended to identify forward-looking statements that represent our current judgment about possible future events. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: demand for and market acceptance of risks for new and existing products; product development risks; product quality or patient safety concerns; future actions of regulatory bodies and other governmental authorities, including FDA, the Department of Justice, the New York Attorney General and foreign regulatory agencies (with respect to the Warning Letter or otherwise); accurate identification of and execution on business development and R&D opportunities and realization of anticipated benefits; the adequacy of the company s cash flows from operations to meet its ongoing cash obligations and fund its investment program; and other risks identified in Baxter s most recent filing on Form 10-K and other Securities and Exchange Commission filings, all of which are available on Baxter s website. Baxter does not undertake to update its forward-looking statements.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 17, 2018

BAXTER INTERNATIONAL INC.

/s/ James K. Saccaro
By: James K. Saccaro