

Mylan N.V.
Form 8-K
June 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): June 13, 2018

Mylan N.V.

(Exact name of registrant as specified in its charter)

The Netherlands
(State or Other Jurisdiction

of Incorporation)

333-199861
(Commission

File Number)

98-1189497
(I.R.S. Employer

Identification No.)

Building 4, Trident Place, Mosquito Way,

Hatfield, Hertfordshire
(Address of Principal Executive Offices)
+44 (0) 1707 853 000

AL10 9UL
(Zip Code)

(Registrant's telephone number, including area code)

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 7.01 Regulation FD Disclosure.

Mylan Provides Statement on Generic Advair Diskus®

On the afternoon of June 13, 2018, we received an update from the U.S. Food & Drug Administration (FDA) concerning our pending approval for Generic Advair Diskus® that FDA has identified minor deficiencies to be relayed in a Complete Response Letter on June 27, 2018. Because our Abbreviated New Drug Application has received a priority designation, our approval could be received prior to the standard 90-day time period following the date of our response to the Complete Response Letter.

Upon receipt of the official Complete Response Letter, we will determine what, if any, impact that it could have on our full year 2018 outlook.

This information includes statements that constitute forward-looking statements , including with regard to product approvals and outlook. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

The information contained in this Item 7.01 of this Current Report on Form 8-K shall not be deemed filed with the Securities and Exchange Commission nor incorporated by reference in any registration statement filed by the Company under the Securities Act of 1933, as amended.

SIGNATURE

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.

MYLAN N.V.

Date: June 13, 2018

By: /s/ Kenneth S. Parks
Kenneth S. Parks

Chief Financial Officer