Mylan N.V.
Form 8-K
October 07, 2016

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):

October 7, 2016

MYLAN N.V.

(Exact name of registrant as specified in its charter)

The Netherlands	**333-199861**	**98-1189497**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Building 4, Trident Place

Mosquito Way, Hatfield, Hertfordshire **AL10 9UL**
(Address of Principal Executive Offices) **(Zip Code)**
+44 (0) 1707 853 000

(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))

Item 2.02 Results of Operations and Financial Condition.

On October 7, 2016, Mylan N.V. (Mylan) issued a press release that included information regarding the quarter ended September 30, 2016. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

Item 2.02 of this report is incorporated by reference into this Item 7.01. The press release also announced that Mylan had agreed to the terms of a $465 million settlement with the U.S. Department of Justice and other government agencies that will resolve questions that have been raised about the classification of the EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector (collectively, EpiPen Auto-Injector) for purposes of the Medicaid Drug Rebate Program.

The terms of the settlement do not provide for any finding of wrongdoing on the part of Mylan Inc. or any of its affiliated entities or personnel. The question in the underlying matter was whether EpiPen Auto-Injector was properly classified with the Centers for Medicaid and Medicare Services (CMS) as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs. EpiPen Auto-Injector has been classified with CMS as a non-innovator drug since before Mylan acquired the product in 2007 based on longstanding written guidance from the federal government.

The settlement terms provide for resolution of all potential rebate liability claims by federal and state governments as to whether the product should have been classified as an innovator drug for CMS purposes, and subject to a higher rebate formula. Consistent with the recent CMS rule regarding the classification of drugs for rebate purposes, EpiPen Auto-Injector will begin being classified as an innovator drug on April 1, 2017. In connection with the settlement, Mylan expects to enter into a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. Mylan will continue to work with the government to finalize the settlement.

Also on October 7, 2016, Mylan received a document request from the Division of Enforcement at the Securities and Exchange Commission (SEC) seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaints. Mylan intends to fully cooperate with the SEC s investigation.

The information in Items 2.02 and 7.01 (including Exhibit 99.1) shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated October 7, 2016.

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: October 7, 2016

By: /s/ Kenneth S. Parks
Kenneth S. Parks
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated October 7, 2016.