Mylan N.V.
Form 8-K
August 21, 2017

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 16, 2017

MYLAN N.V.

(Exact Name of Registrant as Specified in 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)**
Registrant s telephone number, including area code: +44 (0) 1707-853-000

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 1.01. Entry into a Material Definitive Agreement.

On August 17, 2017, Mylan N.V. (the Company) announced that its subsidiaries, Mylan Inc. and Mylan Specialty L.P. (together, Mylan), have signed an agreement with the U.S. Department of Justice (DOJ) and two relators finalizing the Medicaid drug rebate settlement, which the Company had previously announced on October 7, 2016, for $465 million (the Settlement Agreement).

As previously disclosed, the Settlement Agreement resolves claims relating to the classification of EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector (collectively, EpiPen® Auto-Injector) for purposes of the Medicaid Drug Rebate Program. The question in the underlying matter was whether the EpiPen® products were properly classified with the Centers for Medicare and Medicaid 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 Specialty L.P. acquired the product in 2007 based on longstanding written guidance from the federal government.

The Settlement Agreement provides for resolution of all potential Medicaid rebate liability claims by the federal government, as well as potential claims by certain hospitals and other covered entities that participate in the 340B Drug Pricing Program. The Settlement Agreement allocates money to the Medicaid programs of all 50 states and establishes a framework for resolving all potential state Medicaid rebate liability claims within 60 days. In connection with the settlement, Mylan also has entered into a Corporate Integrity Agreement (the CIA) with the Office of Inspector General of the Department of Health and Human Services (OIG-HHS) which has a five-year term and which requires, among other things, that an independent review organization annually review various matters relating to Mylan and the Medicaid drug rebate program.

Neither the Settlement Agreement nor the CIA contains an admission or finding of wrongdoing. Mylan Specialty L.P. will reclassify EpiPen® Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017. As disclosed in our Quarterly Report on Form 10-Q filed on August 9, 2017, in anticipation of the Settlement Agreement being finalized, the Company has accrued the higher rebate amount since April 1, 2017.

The foregoing descriptions of the Settlement Agreement and the CIA are not complete and are qualified in their entirety by reference to such agreements, which have been available on the DOJ and OIG-HHS websites, respectively, and which are attached to this Form 8-K as Exhibits 10.1 and 10.2, respectively, and are incorporated by reference in this Form 8-K.

Item 7.01. Regulation FD Disclosure.

On August 17, 2017, the Company issued a press release announcing its entry into the Settlement Agreement and the CIA. A copy of that press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 7.01. The information contained in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, 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.

Forward-Looking Statements.

This report and the attachments include statements that constitute forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements in the press release about the Company s commitment to providing patients in the U.S. and around the world with access to medicine, and that the Company looks forward to continuing to deliver on this mission. 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: any changes in or difficulties with our inventory of, and our ability to manufacture and distribute, EpiPen and our other products; the effect of any changes in our customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of the Company; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on our business; any regulatory, legal, or other impediments to our ability to bring our products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; our ability to protect our intellectual property and preserve intellectual property rights; other uncertainties and matters beyond the control of management; and the other risks detailed in the Company s filings with the Securities and Exchange Commission. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Settlement Agreement with the U.S. Department of Justice and two relators finalizing the Medicaid drug rebate settlement, dated August 16, 2017.
10.2	Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Mylan Inc. and Mylan Specialty L.P., dated August 16, 2017.
99.1	Press release dated August 17, 2017.

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: August 21, 2017

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

Chief Financial Officer

EXHIBIT INDEX

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