MYLAN N.V.

FORM 10-K
(Annual Report)

Filed 02/16/16 for the Period Ending 12/31/15

Telephone	44 0 1707 853 000
CIK	0001623613
SIC Code	2834 - Pharmaceutical Preparations
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☑ **Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Fiscal Year Ended December 31, 2015

OR

☐ **Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to .

Commission file number 333-199861

MYLAN N.V.

(Exact name of registrant as specified in its charter)

The Netherlands	**98-1189497**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England

(Address of principal executive offices)

+44 (0) 1707-853-000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Ordinary shares, nominal value €0.01	The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the outstanding ordinary shares, nominal value €0.01 , of the registrant other than shares held by persons who may be deemed affiliates of the registrant, as of June 30, 2015 , the last business day of the registrant's most recently completed second fiscal quarter, was approximately $33,063,308,366 .

The number of ordinary shares outstanding, nominal value €0.01 , of the registrant as of February 8, 2016 was 490,687,866 .

INCORPORATED BY REFERENCE

Document	**Part of Form 10-K into Which Document is Incorporated**
An amendment to this Form 10-K will be filed no later than 120 days after the close of registrant's fiscal year.	III

MYLAN N.V.
INDEX TO FORM 10-K
For the Year Ended December 31, 2015

PART I

ITEM 1. Business

Mylan N.V. , along with its subsidiaries (collectively, the "Company," " Mylan ," "our" or "we"), is a leading global pharmaceutical company, which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. Mylan is committed to setting new standards in healthcare by creating better health for a better world, and our mission is to provide the world's 7 billion people access to high quality medicine. To do so, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership.

Mylan offers one of the industry's broadest product portfolios, including more than 1,400 marketed products, to customers in approximately 165 countries and territories. We operate a global, high quality vertically-integrated manufacturing platform, which includes more than 50 manufacturing and research and development ("R&D") facilities around the world and one of the world's largest active pharmaceutical ingredient ("API") operations. We also operate a strong and innovative R&D network that has consistently delivered a robust product pipeline including a variety of dosage forms, therapeutic categories and biosimilars. Additionally, Mylan has a specialty pharmaceutical business that is focused on respiratory and allergy therapies.

Overview

Throughout its history, Mylan has been recognized as a leader in the United States ("U.S.") generic pharmaceutical industry. Our leadership position is the result of, among other factors, our ability to efficiently obtain Abbreviated New Drug Application ("ANDA") approvals and our reliable high quality supply chain. Mylan is one of the largest generic and specialty pharmaceuticals companies in the world today in terms of revenue and is recognized as an industry leader because of our organic growth and transformative acquisitions beginning in 2007.

On July 13, 2014 , Mylan N.V. and Mylan Inc. entered into a definitive agreement, as amended on November 4, 2014 , with Abbott Laboratories (" Abbott ") to acquire Abbott's non-U.S. developed markets specialty and branded generics business (the " EPD Business ") in an all-stock transaction. In connection with the closing of the acquisition on February 27, 2015 (the " EPD Transaction Closing Date "), Abbott transferred the EPD Business to Mylan N.V. in exchange for 110 million ordinary shares of Mylan N.V. Mylan Inc. became an indirect wholly owned subsidiary of Mylan N.V. , and Mylan Inc.'s outstanding common stock was exchanged on a one to one basis for Mylan N.V. ordinary shares.

The purchase price for the acquired EPD Business , which was on a debt-free basis, was $6.3 billion based on the closing price of Mylan Inc.'s stock as of the EPD Transaction Closing Date , as reported by the NASDAQ Global Select Stock Market . On the EPD Transaction Closing Date , Mylan N.V. , Abbott and Abbott Shareholders entered into a shareholder agreement. Following an underwritten public offering of Abbott Shareholders of a portion of Mylan N.V. 's ordinary shares held by them, which closed on April 6, 2015, the Abbott Shareholders currently own approximately 14.2% of Mylan N.V. 's outstanding ordinary shares. The acquired EPD Business enhanced our already expansive product portfolio by more than 100 specialty and branded generic pharmaceutical products in five major therapeutic areas and included several patent protected, novel and/or hard-to-manufacture products. Additionally, we significantly expanded and strengthened our presence in Europe, Japan, Canada, Australia and New Zealand.

On November 20, 2015, we completed the acquisition of certain female healthcare businesses from Famy Care Limited (such businesses " Jai Pharma Limited "), a specialty women's healthcare company with global leadership in generic oral contraceptive products, through our wholly owned subsidiary Mylan Laboratories Limited ("Mylan India") for a cash payment of $750 million plus additional contingent payments of up to $50 million for the filing for approval with, and receipt of approval from, the U.S. Food and Drug Administration ("FDA") of a product under development with Jai Pharma Limited .

In accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), the Company used the purchase method of accounting to account for this transaction. Under the purchase method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at their respective estimated fair values at the acquisition date. The U.S. GAAP purchase price was $711.1 million , which excludes the $50 million paid into escrow at closing that is contingent upon at least one of two principal former shareholders of Jai Pharma Limited continuing to provide consulting services to the acquired business for the two year post-closing period and will be treated as compensation expense over the service period. The U.S. GAAP purchase price also excludes $7 million of working capital and other adjustments and includes estimated contingent consideration of approximately $18 million related to the $50 million contingent payment. With

this transaction, we have significantly broadened our women's care portfolio and strengthened our technical and manufacturing capabilities.

Through these transactions, along with our previous transformative acquisitions of Agila Specialties (‘‘ Agila ’’), Mylan India, Merck KGaA's generics and specialty pharmaceutical business, Bioniche Pharma Holdings Limited (“ Bioniche Pharma ”) and Pfizer Inc.'s respiratory delivery platform (the “respiratory delivery platform”), we have created a horizontally and vertically integrated platform with global scale, augmented our diversified product portfolio and further expanded our range of capabilities, all of which we believe position us well for the future.

Today, in addition to the U.S., Mylan has a robust worldwide commercial presence in the generic pharmaceutical market, including leadership positions in Australia, several key European markets such as France and Italy, as well as other markets around the world. Mylan also is a leader in branded specialty pharmaceuticals focusing on respiratory and allergy products.

Currently, Mylan 's global portfolio of more than 1,400 different marketed products covers a vast array of therapeutic categories. We offer an extensive range of dosage forms and delivery systems, including oral solids, topicals, liquids and semisolids while focusing on those products that are difficult to formulate and manufacture, and typically have longer life cycles than traditional generic pharmaceuticals, including transdermal patches, high potency formulations, injectables, controlled-release and respiratory products. In addition, we offer a wide range of antiretroviral therapies (“ARVs”), upon which nearly 50% of patients being treated for HIV/AIDS in developing countries depend. Mylan also operates one of the largest API manufacturers, supplying low cost, high quality API for our own products and pipeline as well as for a number of third parties.

We believe that the breadth and depth of our business and platform provide certain competitive advantages in major markets in which we operate, including less dependency on any single market or product. As a result, we are better able to successfully compete on a global basis than compared to many of our competitors.

Our Operations

Mylan N.V. was originally incorporated as a private limited liability company, New Moon B.V., in the Netherlands in 2014. Mylan became a public limited liability company in the Netherlands through its acquisition of the EPD Business on February 27, 2015 . Mylan's corporate seat is located in Amsterdam, the Netherlands , its principal executive offices are located in Hatfield, Hertfordshire, England and Mylan N.V. group's global headquarters are located in Canonsburg, Pennsylvania . Mylan operates in two segments, “Generics” and “Specialty.” Our revenues are derived primarily from the sale of generic and branded generic pharmaceuticals, specialty pharmaceuticals and API. Our generic pharmaceutical business is conducted primarily in the U.S. and Canada (collectively, “North America”); Europe; and India, Australia, Japan, New Zealand and Brazil as well as our export activity into emerging markets (collectively, “Rest of World”). Our API business is conducted through Mylan India , which is included within Rest of World in our Generics segment. Our specialty pharmaceutical business is conducted by Mylan Specialty L.P. (“ Mylan Specialty ”). Refer to Note 13 *Segment Information* included in Item 8 in this Form 10-K for additional information related to our segments, including our geographic markets.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.