MYLAN INC.

FORM 10-K
(Annual Report)

Filed 02/28/13 for the Period Ending 12/31/12

Address	1500 CORPORATE DRIVE CANONSBURG, PA 15317
Telephone	724-514-1800
CIK	0000069499
Symbol	MYL
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
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, 2012

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 1-9114

MYLAN INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	**25-1211621**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

1500 Corporate Drive, Canonsburg, Pennsylvania 15317
(Address of principal executive offices)
(724) 514-1800
(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:**
Common Stock, par value $0.50 per share	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 common stock, other than shares held by persons who may be deemed affiliates of the registrant, as of June 30, 2012 , the last business day of the registrant's most recently completed second fiscal quarter, was approximately $8,624,667,439 .

The number of shares outstanding of common stock of the registrant as of February 25, 2013 , was 395,550,874 .

INCORPORATED BY REFERENCE

Document	**Part of Form 10-K into Which Document is Incorporated**
Proxy Statement for the 2013 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2012.	III

NCI Exhibit 2013

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For the Year Ended December 31, 2012

PART I

ITEM 1. Business

Mylan Inc. along with its subsidiaries (collectively, the "Company," "Mylan," "our" or "we") is a fully integrated global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. Mylan ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in approximately 140 countries and territories. We maintain one of the industry's broadest and highest quality product portfolios, supported by a robust product pipeline and one of the world's largest vertically integrated active pharmaceutical ingredient ("API") operations. Additionally, we operate a specialty business which is focused on respiratory, allergy and psychiatric therapies. Mylan was incorporated in Pennsylvania in 1970 .

Overview

Throughout its history, Mylan has been recognized as a leader in the United States ("U.S.") generic pharmaceutical market. Since 2007, Mylan has transformed itself and today is one of the largest generic and specialty pharmaceuticals companies in the world in terms of revenue. This transformation has taken place through organic growth and external expansion. Our leadership position in the U.S. generic pharmaceutical industry is the result of our ability to obtain Abbreviated New Drug Application ("ANDA") approvals, as well as our reliable and high quality supply chain. Through the acquisitions of Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited), Merck KGaA's generics and specialty pharmaceutical business (the "former Merck Generics business"), Bioniche Pharma Holdings Limited ("Bioniche Pharma") and Pfizer Inc.'s ("Pfizer's") 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.

In addition to the U.S., Mylan has a robust worldwide commercial presence in the generic pharmaceutical market, including leadership positions in France and Australia and several other key European and Asia Pacific markets, as well as a leading branded specialty pharmaceutical business focusing on respiratory, allergy and psychiatric products.

Currently, Mylan markets a global portfolio of approximately 1,100 different products covering a vast array of therapeutic categories. We offer an extensive range of dosage forms and delivery systems, including oral solids, topicals, liquids and semi-solids. In addition, we focus on those that are difficult to formulate and manufacture and typically have longer product life cycles than traditional generic pharmaceuticals, including transdermal patches, high potency formulations, injectables, controlled-release and respiratory products. Mylan also manufactures and supplies low cost, high quality API for its own products and pipeline, as well as for third parties.

Mylan also has one of the deepest pipelines and largest number of products pending regulatory approval in our history. Increasing sales volumes and continuing leverage of our vertically integrated platform provides substantial operational efficiencies and economies of scale.

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

Our Operations

Mylan has two segments, "Generics" and "Specialty." Our revenues are primarily derived 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, the Middle East, and Africa (collectively, "EMEA"); and India, Australia, Japan and New Zealand (collectively, "Asia Pacific"). Our API business is conducted through Mylan Laboratories Limited ("Mylan India"), which is included within the Asia Pacific region in our Generics Segment. Our specialty pharmaceutical business is conducted by Mylan Specialty L.P. ("Mylan Specialty"). Refer to Note 13 to Consolidated Financial Statements included in Item 8 in this Form 10-K for additional information related to our segments.

Generics Segment

North America

The U.S. generics market is the largest in the world, with generic prescription market sales of $46.0 billion for the twelve months ended November 2012 . Mylan holds the number two ranking in the U.S. generics prescription market in terms of both sales and prescriptions dispensed. One in every 11 prescriptions dispensed in the U.S. is a Mylan product. Our sales in the U.S. are derived principally through our wholly owned subsidiary Mylan Pharmaceuticals Inc. ("MPI"), our primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary, as well as through our wholly owned subsidiary Mylan Institutional ("MI"). MI supplies pharmaceutical products and services to institutional customers, such as group purchasing organizations, hospitals and long-term care facilities.

MPI's net revenues are derived primarily from the sale of solid oral dosage and transdermal patch products. MI's net revenues are derived from the sale of its unit dose and injectable product offerings. In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 365 products, of which approximately 310 are in capsule or tablet form in an aggregate of approximately 880 dosage strengths. Included in these totals are approximately 40 extended-release products in a total of approximately 105 dosage strengths.

Also included in our U.S. product portfolio are three transdermal patch products in a total of 15 dosage strengths that are developed and manufactured by Mylan Technologies, Inc. ("MTI"), our wholly owned transdermal technology subsidiary, and marketed and distributed by MPI. MTI's fentanyl transdermal system ("fentanyl") was the first AB-rated generic alternative to Duragesic® on the market and was also the first generic class II narcotic transdermal product ever approved. MTI's fentanyl product currently remains the only AB-rated generic alternative approved in all strengths.

Mylan Institutional focuses on providing a differentiated product offering tailored to institutional customers throughout North America, including group purchasing organizations, wholesalers, hospitals, surgical services, home infusion service providers, long-term care facilities, correctional facilities, specialty pharmacies and retail outlets. MI markets and repackages products, either obtained from MPI or purchased from third parties, in unit dose form, and manufactures and sells a diverse portfolio of injectable products across several therapeutic areas, with most of the Company's sales made to customers in the U.S. MI also provides a platform for the commercialization of future biogeneric product offerings. MI has, among other product offerings, a diverse portfolio of approximately 40 injectable products (branded and generic) in a total of approximately 60 dosage strengths, across several therapeutic areas for the hospital setting, including analgesics/anesthetics, anti-infections, cardiology and oncology. In addition to the products we manufacture in the U.S., we also market approximately 50 generic products in a total of approximately 75 dosage strengths under supply and distribution agreements with wholesalers.

We believe that the breadth and quality of our product offerings help us to successfully meet our customers' needs and to better compete in the generic industry over the long term. We also believe that the future growth of our U.S. generics business is partially dependent upon continued acceptance of generic products as low cost alternatives to branded pharmaceuticals, a trend which is largely outside of our control. However, we believe that we can maximize the profitability of our generic product opportunities by continuing our proven track record of bringing to market high quality products that are difficult to formulate or manufacture, or for which the API is difficult to obtain. Over the last several years, in addition to fentanyl, we have successfully introduced many generic products with high barriers to entry that continue to be meaningful contributors to our business several years after their initial launch. Additionally, we expect to achieve growth in our U.S. business by launching new products for which we may attain U.S. Food and Drug Administration ("FDA") first-to-file status with Paragraph IV certification. As described further in the "Product Development and Government Regulation" discussion below, this Paragraph IV certification makes the product approval holder eligible for a period of generic marketing and distribution exclusivity.

Our North America revenues also include those generated by our wholly owned subsidiary Mylan Pharmaceuticals ULC ("MPC"), which markets generic pharmaceuticals in Canada, the world's fifth largest generic prescription market by value and the sixth largest generic prescription market by volume with sales of $4.4 billion for the twelve months ended November 2012 . MPC offers a portfolio of approximately 120 products in an aggregate of approximately 300 dosage strengths, and currently ranks fifth in terms of market share in the generic prescription market in Canada. As in the U.S., we believe that growth in Canada will be dependent upon acceptance of generic products as low cost alternatives to branded pharmaceuticals. Further, we plan to leverage the strength and reliability of the Mylan brand in the U.S. to foster growth throughout North America.

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