MYLAN INC.
Form 10-K
March 02, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-K

þ Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended December 31, 2014

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.)

1000 Mylan Boulevard, 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 þ 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 þ

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 þ 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 þ 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. þ

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	þ	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 þ

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, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $19,152,056,870.

The number of shares outstanding of common stock of the registrant as of February 24, 2015 was 378,373,668.

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

EXPLANATORY NOTE

As discussed herein, on February 27, 2015 (the "Closing Date"), Mylan N.V. completed the transaction by which it acquired Mylan Inc. and Abbott Laboratories' non-U.S. developed markets specialty and branded generics business. Pursuant to the terms of the Amended and Restated Business Transfer Agreement and Plan of Merger, dated as of November 4, 2014, by and among Mylan Inc., New Moon B.V. (which has been renamed Mylan N.V.), Moon of PA Inc., and Abbott Laboratories, on the Closing Date, Mylan N.V. acquired Abbott Laboratories' non-U.S. developed markets specialty and branded generics business and Moon of PA Inc. merged with and into Mylan Inc., with Mylan Inc. surviving as a wholly owned indirect subsidiary of Mylan N.V. (the "Merger") and each share of Mylan Inc. common stock issued and outstanding was canceled and automatically converted into and became the right to receive one Mylan N.V. ordinary share. In connection with this transaction, Mylan Inc. and Abbott Laboratories' non-U.S. developed markets specialty and branded generics business were reorganized under Mylan N.V., a new public company organized in the Netherlands. On February 18, 2015, the Office of Chief Counsel of the Division of Corporation Finance of the Securities and Exchange Commission issued a no-action letter to Mylan Inc. and Mylan N.V. that included its views that the Merger constituted a "succession" for purposes of Rule 12g-3(a) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and that Mylan N.V., as successor to Mylan Inc., is deemed a large accelerated filer for purposes of Exchange Act Rule 12b-2. Mylan Inc. is filing this Annual Report on Form 10-K in accordance with Rule 12g-3(g) of the Exchange Act. As of March 2, 2015, Mylan N.V., and not Mylan Inc., traded on the NASDAQ Stock Market under the symbol "MYL".

MYLAN INC.
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For the Year Ended December 31, 2014

PART I

ITEM 1. Business

Unless otherwise indicated, the following discussion relates to Mylan Inc. prior to the consummation of the Transaction, defined below, on February 27, 2015.

Mylan Inc., 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 health care 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 approximately 1,400 marketed products, to customers in approximately 140 countries and territories. With the completion of the Abbott Laboratories ("Abbott") transaction discussed below, Mylan has expanded its global footprint to reach customers in approximately 145 countries and territories. We operate a global, high quality vertically-integrated manufacturing platform, which includes approximately 40 manufacturing facilities around the world and one of the world's largest active pharmaceutical ingredient ("API") operations. We also operate a strong research and development ("R&D") network that has consistently delivered a robust product pipeline. Additionally, Mylan has a specialty 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.

Through organic growth and transformative acquisitions since 2007, Mylan is one of the largest generic and specialty pharmaceuticals companies in the world today in terms of revenue and is now recognized as an industry leader globally.

On July 13, 2014, the Company entered into a definitive agreement with Abbott to acquire Abbott's non-U.S. developed markets specialty and branded generics business (the "Business") in an all-stock transaction. On November 4, 2014, the Company and Abbott entered into an amended and restated definitive agreement implementing the transaction (the "Transaction Agreement"). The transaction, defined below, closed on February 27, 2015 after receiving approval from Mylan's shareholders on January 29, 2015. At closing, Abbott transferred the Business to Mylan N.V., ("New Mylan") in exchange for 110 million ordinary shares of New Mylan. Immediately following the transfer of the Business, Mylan merged with a wholly owned subsidiary of New Mylan (together with the transfer of the Business, the "Transaction"), with Mylan becoming a wholly owned indirect subsidiary of New Mylan. Mylan's outstanding common stock was exchanged on a one to one basis for New Mylan ordinary shares. As a result of the Transaction, New Mylan's corporate seat is located in Amsterdam, the Netherlands, and its principal executive offices are located in Potters Bar, United Kingdom. New Mylan will also have global centers of excellence in the U.S., Europe and India.

The Business includes more than 100 specialty and branded generic pharmaceutical products in five major therapeutic areas and includes several patent protected, novel and/or hard-to-manufacture products. As a result of the acquisition, Mylan N.V. has significantly expanded and strengthened its product portfolio in Europe, Japan, Canada, Australia and New Zealand.

The purchase price of the Transaction, which was on a debt-free basis, was $6.31 billion based on the closing price of Mylan stock as of the Transaction closing date, as reported by the NASDAQ Stock Market. As a result of the Transaction, Mylan shareholders own approximately 78% of New Mylan and Abbott's affiliates own approximately 22% of New Mylan. New Mylan and Abbott entered into a shareholder agreement in connection with the Transaction.

Through this Transaction, along with previous transformative acquisitions of Agila Specialties (''Agila''), Mylan Laboratories Limited ("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, augmenting our diversified product portfolio and further expanding 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 France and Australia and several other key European markets as well as markets around the world. Mylan is also a leader in branded specialty pharmaceuticals focusing on respiratory and allergy products.

Currently, Mylan markets a global portfolio of approximately 1,400 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 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 approximately 40% of HIV/AIDS patients 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 was incorporated in Pennsylvania in 1970 and maintains its principal executive offices 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 12 for Consolidated Financial Statements included in Item 8 in this Form 10-K for additional information related to our segments, including our geographic markets.

Our global operational footprint, including the locations of our manufacturing facilities, global R&D centers of excellence and technology focused development sites, along with the sites' primary activities, are detailed on the map below:

Our global manufacturing platform is an important component of our business model. We own six production, distribution and warehousing facilities in the U.S. and Puerto Rico, including significant production and distribution sites in Morgantown, West Virginia; St. Albans, Vermont; Caguas, Puerto Rico; and Greensboro, North Carolina. Outside the U.S. and Puerto Rico, we own production, distribution and warehousing facilities in nine countries, including key facilities in India, Australia, Japan, Ireland, Brazil, Hungary, Poland and France. In addition, as a result of the Transaction, the Company acquired two high-quality manufacturing facilities in Chatillon, France and Katsuyama, Japan.

The Company also leases warehousing, distribution and administrative facilities in numerous locations, within and outside of the U.S., including properties in New York, France, India, Ireland and the United Kingdom ("U.K."). All of the production, distribution and warehousing facilities are included within the Generics segment; however, certain locations also support our Specialty segment.

Our global R&D centers of excellence are located in Morgantown, West Virginia and Hyderabad, India. We also have specific R&D technology centers of excellence in Ireland, India, the U.K. and Japan. As a result of the Transaction, New Mylan's corporate seat is located in Amsterdam, the Netherlands, and its principal executive offices are located in Potters Bar, United Kingdom. New Mylan will also have global centers of excellence in the U.S., Europe and India.

We believe that all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.

Generics Segment
North America
The U.S. generics market is the largest in the world, with generic prescription sales of $55.6 billion for the twelve months ended November 2014. Mylan holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed. Approximately one in every 13 prescriptions dispensed in the U.S. is a Mylan product. Our sales in the U.S. are derived primarily from the sale of oral solid dosage, injectable and transdermal products and unit dose offerings. In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 360 products, of which approximately 270 are in capsule or tablet form, in an aggregate of approximately 815 dosage strengths. Included in these totals are approximately 45 extended-release products in a total of approximately 105 dosage strengths.

We manufacture and sell a diverse portfolio of injectable products across several key therapeutic areas, including antineoplastics, anti-infectives, anesthesia/pain management and cardiovascular. Our product offerings include a diverse portfolio of approximately 125 injectable products (branded and generic) in a total of approximately 175 dosage strengths. As of December 31, 2014, approximately 120 injectable products have been filed and are pending ANDA approval for the U.S. market. Mylan's injectable manufacturing capabilities include vials, pre-filled syringes, ampoules and lyophilization with a focus on antineoplastics, penems, penicillins, ophthalmics and peptides.

Our unit dose business focuses on providing one of the largest product portfolios along with innovative packaging and barcoding that supports bedside verification throughout the U.S. and Canada for hospitals, group purchasing organizations ("GPOs"), long term care facilities, wholesalers, surgical services, home infusion service providers, correctional facilities, specialty pharmacies and retail outlets. In addition to the products we package in the U.S., we also market approximately 60 generic products in a total of approximately 80 dosage strengths under supply and distribution agreements with wholesalers. Also included in our U.S. product portfolio are five transdermal patch products in a total of 25 dosage strengths, including our Fentanyl Transdermal System ("Fentanyl") which 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.

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. The future growth of our U.S. generics business is partially dependent upon continued acceptance of generic products as affordable 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. Over the last several years we have successfully introduced many generic products that are difficult to formulate or manufacture and 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, Paragraph IV certification qualifies the product approval holder for a period of generic marketing and distribution exclusivity.

In Canada, we offer a portfolio of approximately 170 products in an aggregate of approximately 375 dosage strengths and currently rank seventh in terms of market share in the generic prescription market. As in the U.S., growth in Canada will be dependent upon acceptance of generic products as affordable alternatives to branded pharmaceuticals. Further, we plan to

leverage the strength and reliability of the Mylan brand to foster growth throughout the region. With the acquisition of Agila, we further diversified our pharmaceutical portfolio by adding generic injectable products in the Canadian market.

Europe

Our generic pharmaceutical sales in Europe are generated primarily by our wholly owned subsidiaries, through which we have operations in 22 countries. The types of markets within Europe vary from country to country; however, when combined, the European market is the second largest generic pharmaceutical market in the world in terms of value. Within Europe, by value, the generic prescription market in Germany is the largest, followed by the U.K., France, Spain and Italy, respectively. Of the top ten generic prescription markets in Europe, we hold leadership positions in several markets, described below, including the number one market share position in France, the number two market share position in Italy and the number three market share position in Portugal.

The European generic prescription market varies significantly by country in terms of the extent of generic penetration, the key decision maker in terms of drug choice and other important aspects. Some countries, including Germany, the U.K., the Netherlands and Poland, are characterized by relatively high generic penetration, ranging between 66% and 72% of total prescription market sales in the twelve months ended November 2014, based on volume. Conversely, other major European markets, including France, Italy and Spain, are characterized by much lower generic penetration, ranging between 19% and 40% of total prescription sales in the twelve months ended November 2014, based on volume. However, recent actions taken by governments, particularly in these latter under-penetrated countries, to reduce health care costs could encourage further use of generic pharmaceutical products. In each of these under-penetrated markets, in addition to growth from new product launches, we expect our future growth to be driven by increased generic utilization and penetration.

The manner in which products are marketed also varies by country. In addition to selling pharmaceuticals under their International Nonproprietary Name (“INN”) (i.e., API), in certain European countries, there is a market for both branded generic products and “company-branded” generic products. Branded generic pharmaceutical products are given a unique brand name, as these markets tend to be more responsive to the promotion efforts generally used to promote brand products. Company-branded products generally consist of the name of the active ingredient with a prefix or suffix of the company’s name, either in whole or in part.

France

In France, we market a portfolio, including both oral solid and injectable dosage forms, of approximately 300 products in an aggregate of approximately 670 dosage strengths. We have the highest market share in the generic market, with a share of approximately 26%. Our future growth in the French market is expected to come primarily from new product launches and increased generic utilization and penetration through government initiatives.

Italy

In Italy, we market a portfolio of approximately 170 products in an aggregate of approximately 340 dosage strengths. We have the second highest market share in the company-branded generic prescription market, with a share of approximately 19%. We believe that the Italian generic market is under-penetrated, with company-branded generics representing approximately 20% of the Italian pharmaceutical market, based on volume. The Italian government has put forth only limited measures aimed at encouraging generic use, and as a result, generic substitution is still in its early stages. Our growth in the Italian generics market will be fueled by increasing generic utilization and penetration and new product launches.

United Kingdom

In the U.K., we market a portfolio of approximately 185 products in an aggregate of approximately 350 dosage strengths. Mylan is ranked fourth in the U.K. generic prescription market, in terms of value, with an estimated market

share of approximately 6%. Mylan is well positioned in the U.K. as a preferred supplier to wholesalers and is also focused on areas such as multiple retail pharmacies and hospitals. The U.K. generic prescription market is highly competitive, and any growth in the market will stem from new product launches although we expect that the value will continue to be affected by price erosion.

Spain

In Spain, we market a portfolio of approximately 135 products in an aggregate of approximately 290 dosage strengths. We have the seventh highest market share in the company-branded generic prescription market. The company-branded generic market comprised approximately 34% of the total Spanish pharmaceutical market by volume for the twelve months ended

November 2014. We view further generic utilization and penetration of the Spanish market to be a key driver of our growth in that country.

The Netherlands
In the Netherlands, we market a portfolio of approximately 230 products in an aggregate of approximately 480 dosage strengths. We have the fourth largest market share in the generic prescription market. The Netherlands is characterized by relatively high generic penetration representing approximately 67% of total prescription market sales in the twelve months ended November 2014, based on volume.

Germany
In Germany, we market a portfolio of approximately 145 products in an aggregate of approximately 320 dosage strengths. A tender system has been implemented in Germany and, as a result, health insurers play a major role in this market. Under a tender system, health insurers invite manufacturers to submit bids that establish prices for generic pharmaceuticals. Pricing pressures result from an effort to win the tender. As a result of these tenders, our business in Germany has grown, and future growth in the German marketplace will depend upon our ability to compete based primarily on price.

Poland
As part of the acquisition of Agila, we acquired an injectable manufacturing facility in Poland. In addition, we also operate a commercial business in Poland focused on the generic prescription market. Our future growth is expected to come from increasing the production capacity of our injectable facility and through new product launches.

Other European Locations
We have a notable presence in other European generic prescription markets, including Portugal, where we hold the third highest market share in terms of value. We also operate in several other European markets, including Ireland, the Nordic countries (principally Sweden and Finland), Belgium, the Czech Republic and Hungary.

Rest of World
We market generic pharmaceuticals in Rest of World through subsidiaries in India, Australia, Japan, New Zealand, Brazil and Taiwan. Additionally, we have an export business which is focused on countries in Africa and emerging markets throughout the world. We also participate in a collaboration with Pfizer Japan Inc. (“Pfizer Japan”) to develop, manufacture, distribute and market generic drugs in Japan. Additionally, through Mylan India, we market API to third parties and also supply other Mylan subsidiaries. We have the highest market share in both the Australian and New Zealand generic pharmaceuticals markets.

India
Mylan India manufactures and supplies low cost, high quality API for our own products and pipeline, as well as for numerous third parties. Mylan India is one of the world's largest API manufacturers as measured by the number of drug master files (“DMFs”) filed with regulatory agencies. Mylan India also produces a line of finished dosage form (“FDF”) products for the ARV market, which are sold mostly outside of India. Additionally, Mylan India manufactures non-ARV FDF products that are marketed and sold to third parties by other Mylan operations around the world. Expansion of Mylan India’s portfolio and an increase in product sales within India are both key drivers of our future growth.

We currently have over 300 APIs in the market or under development and we focus our marketing efforts on regulated markets such as the U.S. and the European Union (the “EU”). We produce API for use in the manufacture of our own pharmaceutical products, as well as for use by third parties, in a wide range of categories, including anti-bacterials, central nervous system agents, anti-histamine/anti-asthmatics, cardiovasculars, anti-virals, anti-diabetics, anti-fungals, proton pump inhibitors and pain management drugs.

Mylan India has nine API and intermediate manufacturing facilities, four FDF facilities and eight injectable facilities. All of these facilities are located in India. Eight of the API facilities, two FDF facilities and four injectable facilities have been successfully inspected by the FDA, which makes Mylan India one of the largest companies in India in terms of API manufacturing facilities that have passed FDA inspection. From an API standpoint, growth is dependent upon us continuing to

leverage our R&D capabilities to produce high quality, low cost API, while capitalizing on the greater API volumes afforded through our vertically integrated platform.

In August 2012, Mylan commenced commercial operations in India starting with the launch of a comprehensive portfolio of FDF ARV products for the treatment of HIV/AIDS. In June 2013, Mylan added a portfolio of women's health care products focused on hormone and infertility treatments along with nutritional supplements. During December 2013, the portfolio was further enhanced by adding products from therapeutic categories such as oncology and critical care.

Australia

The generic pharmaceutical market in Australia had sales of approximately $1.9 billion during the twelve months ended November 2014. Our Australian operation has the highest market share in the generic market with an estimated 31% market share by volume and we offer a portfolio of approximately 180 products in an aggregate of approximately 375 dosage strengths. The Australian generics market is still underdeveloped and, as a result, the government is increasingly focused on encouraging the use of generics in an effort to reduce costs. Maintaining our position of market leadership as the market undergoes further generic utilization and penetration and continued pricing pressure will be instrumental to our future success in Australia.

Japan

Beginning in 2013, we established an exclusive long-term strategic collaboration with Pfizer Japan to develop, manufacture, distribute and market generic drugs in Japan. Under the agreement, both parties operate separate legal entities in Japan and collaborate on current and future generic products, sharing the costs and profits resulting from such collaboration. Mylan's responsibilities in Japan primarily consist of managing operations, including R&D and manufacturing. Pfizer Japan's responsibilities primarily consist of the commercialization of the combined generics portfolio and managing a combined marketing and sales effort.

In Japan, together with our partner Pfizer Japan, we offer a broad portfolio of more than 290 products in an aggregate of approximately 450 dosage strengths. We also have a manufacturing and packaging facility located in Japan, which is key to supplying our collaboration in Japan. Japan is the second largest pharmaceutical market in the world by value, behind the U.S., and the seventh largest generic prescription market worldwide by value, with sales of approximately $5.3 billion during the twelve months ended November 2014. Currently, the market is largely composed of hospitals and clinics, but pharmacies are expected to play a greater role as generic substitution, aided by recent pro-generics government action, becomes more prevalent. The Japanese government has stated that it intends to grow the generic share to 60% or higher by the end of March 2018. As of July 2014, the generic share reached 55%, up from approximately 47% at the end of 2013.

New Zealand

In New Zealand, we are the largest generics company in the country, with 28% of the market share by volume. New Zealand is a government tender market where pharmaceutical suppliers can gain exclusivity of up to three years. New Zealand offers a portfolio of approximately 90 products in an aggregate of approximately 150 dosage strengths.

Brazil

We began commercial operations in Brazil in the fourth quarter of 2013 through the acquisition of Agila. In this market, we operate both a manufacturing platform and a commercial business focused on providing high quality generic injectable products to the Brazilian hospital segment. Our sales into this market segment are made through distributors as well as through tenders. Our goal is to build upon this local platform in order to further access the $22 billion Brazilian pharmaceutical market. We are actively working to utilize our global R&D and manufacturing capabilities, along with our robust and differentiated product portfolio to meaningfully expand our hospital offerings in key therapeutic areas. In addition, we continue to explore opportunities to further leverage the Mylan platform and

expand to other dosage forms and product offerings in Brazil.

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector. During 2014, the EpiPen® Auto-Injector became the first Mylan product to reach $1 billion in annual net sales.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

Perforomist® Inhalation Solution, Mylan Specialty's Formoterol Fumarate Inhalation Solution, was launched in October 2007. Perforomist® Inhalation Solution is a long-acting beta2-adrenergic agonist indicated for long-term, twice-daily administration in the maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disorder ("COPD") patients, including those with chronic bronchitis and emphysema. Mylan Specialty has been issued several U.S. and international patents protecting Perforomist® Inhalation Solution.

In addition to EpiPen® Auto-Injector and Perforomist® Inhalation Solution, Mylan Specialty also markets ULTIVA®, which is an analgesic agent used during the induction and maintenance of general anesthesia for inpatient and outpatient procedures and is generally administered by an infusion device.

We believe that we can continue to drive the long-term growth of our Specialty segment by successfully managing our existing product portfolio and bringing to market additional products.

Product Development and Government Regulation
Generics Segment
North America
Prescription pharmaceutical products in the U.S. are generally marketed as either brand or generic drugs. Brand products are usually marketed under brand names through marketing programs that are designed to generate physician and consumer loyalty. Brand products generally are patent protected, which provides a period of market exclusivity during which time they are sold with little or no competition for the compound, although there typically are other participants in the therapeutic area. Additionally, brand products may benefit from other periods of non-patent market exclusivity. Exclusivity normally provides brand products with the ability to maintain their profitability for relatively long periods of time and brand products typically continue to play a significant role in the market due to physician and consumer loyalties after the end of patent protection or other market exclusivities.

Generic pharmaceutical products are the pharmaceutical and therapeutic equivalents of the brand or a reference listed drug ("RLD"). A reference listed brand drug is an approved drug product listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, popularly known as the "Orange Book." The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") provides that generic drugs may enter the market after the approval of an ANDA, which requires that bioequivalence to a reference brand drug be demonstrated and the expiration, invalidation or non-infringement of any patents on the corresponding reference brand drug, or the end of any other relevant market exclusivity periods related to the reference brand drug. Generic drugs are bioequivalent to their reference brand name counterparts. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these reference brand products. Branded generic pharmaceutical products are generic products that are more responsive to the promotion efforts generally used to promote brand products. Growth in