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MYLAN INC.
Form 10-K
March 02, 2015

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, 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 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

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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, 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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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

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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 the generic pharmaceutical industry has been, and will continue to be, driven by the increased market acceptance of generic drugs, as well as the number of brand drugs for which patent terms and/or other market exclusivities have

expired.

We obtain new generic products primarily through internal product development. Additionally, we license or co-develop products through arrangements with other companies. All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

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New Drug Application (“NDA”) — An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system or a new indication for a previously approved drug.

ANDA — An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the FDA’s Orange Book or for a new dosage strength for a drug previously approved under an ANDA.

The ANDA development process is generally less time-consuming and complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the RLD previously approved through the NDA process. The ANDA process, however, does typically require one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved reference listed brand drug. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the RLD product containing the same active ingredient. Bioavailability is a measure of the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. Thus, a demonstration of bioequivalence confirms the absence of a significant difference between the proposed product and the reference listed brand drug in terms of the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action when administered at the same molar dose under similar conditions.

Generic products are generally introduced to the marketplace at the expiration of patent protection for the brand product or at the end of a period of non-patent market exclusivity. However, if an ANDA applicant files an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed in the Orange Book with respect to a reference drug product, the applicant may be able to market the generic equivalent prior to the expiration of patent protection for the brand product. Such patent certification is commonly referred to as a Paragraph IV certification. If the holder of the NDA sues, claiming infringement or invalidation, within 45 days of notification by the applicant, the FDA may not approve the ANDA application until the earlier of the rendering of a court decision favorable to the ANDA applicant or the expiration of 30 months. An ANDA applicant that is first to file a Paragraph IV certification is eligible for a period of generic marketing exclusivity. This exclusivity, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, lasts for 180 days, during which the FDA cannot grant final approval to other ANDA sponsors holding applications for a generic equivalent to the same reference drug.

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic version product. If the reference drug is a new chemical entity, the FDA may not accept an ANDA for a generic product for up to five years following approval of the NDA for the new chemical entity. If it is not a new chemical entity, but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for reference NDA product before the expiration of three years. Certain other periods of exclusivity may be available if the RLD is indicated for treatment of a rare disease or the sponsor conducts pediatric studies in accordance with FDA requirements.

Supplemental ANDAs are required for approval of various types of changes to an approved application and these supplements may be under review for six months or more. In addition, certain types of changes may only be approved once new bioequivalence studies are conducted or other requirements are satisfied.

A number of branded pharmaceutical patent expirations are expected over the next several years. These patent expirations should provide additional generic product opportunities. We intend to concentrate our generic product

development activities on branded products with significant sales in specialized or growing markets or in areas that offer significant opportunities and other competitive advantages. In addition, we intend to continue to focus our development efforts on technically difficult-to-formulate products or products that require advanced manufacturing technology.

The Biologic License Application (“BLA”) regulatory pathway was created to review and approve new applications for drugs that are typically produced in living cells. In 2010, in the context of the adoption of the Patient Protection and Affordable Care Act — H.R. 3590 and the Healthcare and Education Reconciliation Act of 2010 — H.R. 4872, an abbreviated pathway for the approval of generic versions of BLA-approved products (“biosimilars”) in the U.S. was created. This happened after legislation or regulatory guidance for abbreviated pathways for generic biologics were adopted in the past years in the EU, Japan and Canada. The FDA is working to implement these provisions and Mylan is a very active participant in this process.

An additional requirement for FDA approval of NDAs and ANDAs is that our manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as current Good Manufacturing Practices

(“cGMP”). The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the Drug Enforcement Administration (“DEA”) and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

In 2012, the Food and Drug Administration Safety and Innovation Act (“FDASIA”) was enacted into law. FDASIA is intended to enhance the safety and security of the U.S. drug supply chain by holding all drug manufacturers supplying products to the U.S. to the same FDA inspection standards. Specifically, prior to the passage of FDASIA, U.S. law required U.S. based manufacturers to be inspected by FDA every two years but remained silent with respect to foreign manufacturers, causing some foreign manufacturers to go as many as nine years without a routine FDA cGMP inspection, according to the Government Accountability Office.

FDASIA also includes the Generic Drug User Fee Agreement (“GDUFA”), a novel user fee program to provide FDA with approximately \$1.5 billion in total user fees through 2018 focused on three key aims:

Safety – Ensure that industry participants, foreign or domestic, are held to consistent quality standards and are inspected with foreign and domestic parity using a risk-based approach.

Access – Expedite the availability of generic drugs by bringing greater predictability to the review times for abbreviated new drug applications, amendments and supplements and improving timeliness in the review process.

Transparency – Enhance FDA’s visibility into the complex global supply environment by requiring the identification of facilities involved in the manufacture of drugs and associated APIs, and improve FDA’s communications and feedback with industry.

Under GDUFA, 70% of the total fees are being derived from facility fees paid by FDF manufacturers and API facilities listed or referenced in pending or approved generic drug applications. The remaining 30% of the total fees are being derived from application fees, including generic drug application fees, prior approval supplement fees and DMF fees.

In Canada, the registration process for approval of all generic pharmaceuticals has two tracks that proceed in parallel. The first track of the process involves an examination of the proposed generic product by Health Canada, the Federal department responsible for national public health, to ensure that the quality, safety and efficacy of the proposed generic product meets Canadian standards and bioequivalence requirements and the second track concerns patent rights of the brand drug owner. Companies may submit an application called an abbreviated new drug submission (“ANDS”) to Health Canada for sale of the drug in Canada by comparing the drug to another drug marketed in Canada under a Notice of Compliance (“NOC”) issued to a first person. When Health Canada is satisfied that the generic pharmaceutical product described in the ANDS satisfies the statutory requirements, it issues an NOC for that product for the uses specified in the ANDS, subject to any court order that may be made in the second track of the approval process.

The second track of the approval process is governed by the Patented Medicines NOC Regulations (“Regulations”). The owner or exclusive licensee of patents relating to the brand drug for which it has an NOC may have established a list of patents administered by Health Canada enumerating all the patents claiming the medicinal ingredient, formulation, dosage form or the use of the medicinal ingredient. It is possible that even though the patent for the API may have expired, the originator may have other patents on the list which relate to new forms of the API, a formulation or additional uses. Most brand name drugs have an associated patent list containing one or more unexpired patents claiming the medicinal ingredient itself or a use of the medicinal ingredient (a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its

symptoms). In its ANDS, a generic applicant must make at least one of the statutory allegations with respect to each patent on the patent list, for example, alleging that the patent is invalid or would not be infringed and explaining the basis for that allegation. In conjunction with filing its ANDS, the generic applicant is required to serve the originator a Notice of Allegation (“NOA”), which gives a detailed statement of the factual and legal basis for its allegations in the ANDS. The originator may commence a court application within 45 days after it has been served with the NOA, if it takes the position that the allegations are not justified. When the application is filed in court and served on Health Canada, Health Canada may not issue an NOC until the earlier of the determination of the application by the court after a hearing or the expiration of 24 months from the commencement of the application. The period may be shortened or lengthened by the court in certain circumstances. An NOC can be obtained for a generic product only if the generic respondent

is successful in dismissing the application under the Regulations in court. The legal costs incurred in connection with the application could be substantial.

Section C.08.004.1 of the Canadian Food and Drug Regulations is the so-called data protection provision, and the current version of this section applies in respect of all drugs for which an NOC was issued on or after June 17, 2006. A subsequent applicant for approval to market a drug for which an NOC has already been issued does not need to perform duplicate clinical trials similar to those conducted by the first NOC holder, but is permitted to demonstrate safety and efficacy by submitting data demonstrating that its formulation is bioequivalent to the formulation that was issued for the first NOC. The first party to obtain an NOC for a drug will have an eight-year period of exclusivity starting from the date it received its NOC based on those clinical data. A subsequent applicant for approval who seeks to establish safety and efficacy by comparing its product to the product that received the first NOC will not be able to file its own application until six years following the issuance of the first NOC have expired. The Minister of Health will not be permitted to issue an NOC to that applicant until eight years following the issuance of the first NOC have expired — this additional two-year period will correspond in most cases to the 24-month automatic stay under the Regulations. If the first person provides the Minister with the description and results of clinical trials relating to the use of the drug in pediatric populations, it will be entitled to an extra six months of data protection. A drug is only entitled to data protection so long as it is being marketed in Canada.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by Health Canada and the Health Products and Food Branch Inspectorate. In addition, Health Canada conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems are in compliance with the good manufacturing practices in Canada, Drug Establishment Licensing (“EL”) requirements and other provisions of the Regulations. Competitors are subject to similar regulations and inspections.

The provinces and territories in Canada operate drug benefit programs through which eligible recipients receive drugs through public funding; these drugs are listed on provincial or territorial Drug Benefit Formularies (each, a “Formulary”). Eligible recipients include seniors, persons on social assistance, low-income earners and those with certain specified conditions or diseases. Formulary listings are also used by private payors to reimburse generic products. To be listed in a Formulary, drug products must have been issued an NOC and must comply with each jurisdiction’s individual review process.

The primary regulatory approval for pharmaceutical manufacturers, distributors and importers selling pharmaceuticals to be marketed in Canada is the issuance of an EL. An EL is issued once Health Canada has approved the facility in which the pharmaceuticals are manufactured, distributed or imported. A key requirement for approval of a facility is compliance with the good manufacturing practices in Canada. For pharmaceuticals that are imported, the license for the importing facility must list all foreign sites at which imported pharmaceuticals are manufactured. To be listed, a foreign site must demonstrate compliance with the good manufacturing practices in Canada.

Europe

The EU presents complex challenges from a regulatory perspective. There is over-arching legislation which is then implemented at a local level by the 28 individual member states, Iceland, Liechtenstein and Norway. Between 1995 and 1998, the legislation was revised in an attempt to simplify and harmonize product registration. This revised legislation introduced the mutual recognition (“MR”) procedure, whereby after submission and approval by the authorities of the so-called reference member state (“RMS”), further applications can be submitted into the other chosen member states (known as concerned member states (“CMS”). Theoretically, the authorization of the RMS should be mutually recognized by the CMS. More typically, however, a degree of re-evaluation is carried out by the CMS. In November 2005, this legislation was further revised. In addition to the MR procedure, the decentralized procedure (“DCP”) was introduced. The DCP is also led by the RMS, but applications are simultaneously submitted to all selected countries, provided that no national marketing authorization has been granted yet for the medicinal product in

question. From 2005, the centralized procedure operated by the European Medicines Agency (“EMA”) became available for generic versions of innovator products approved through the centralized authorization procedure. The centralized procedure results in a single marketing authorization, which, once granted, can be used by the marketing-authorization holder to file for individual country reimbursement and make the medicine available in all the EU countries listed on the application.

In the EU, as well as many other locations around the world, the manufacture and sale of pharmaceutical products is regulated in a manner substantially similar to that of the U.S. requirements, which generally prohibit the handling, manufacture, marketing and importation of any pharmaceutical product unless it is properly registered in accordance with applicable law. The registration file relating to any particular product must contain medical data related to product efficacy and safety, including results of clinical testing and references to medical publications, as well as detailed information regarding production

methods and quality control. Health ministries are authorized to cancel the registration of a product if it is found to be harmful or ineffective or if it is manufactured or marketed other than in accordance with registration conditions.

Pursuant to the MR procedure, a marketing authorization is first sought in one member state from the national regulatory agency (the RMS). The RMS makes its assessment report on the quality, efficacy and safety of the medicinal product available to the other CMSs where marketing authorizations are also sought under the MR procedure.

The DCP is based on the same fundamental idea as the MR procedure. In contrast to the MR procedure, however, the DCP requires that no national marketing authorization has yet been granted for the medicinal product. The pharmaceutical company applies for marketing authorization simultaneously in all the member states of the EU in which it wants to market the product. After consultation with the pharmaceutical company, one of the member states concerned in the DCP will become the RMS. The competent agency of the RMS undertakes the scientific evaluation of the medicinal product on behalf of the other CMSs and coordinates the procedure. If all the member states involved (RMS and CMS) agree to grant marketing authorizations, this decision forms the basis for the granting of the national marketing authorizations in the respective member states.

Neither the MR nor DCPs result in automatic approval in all member states. If any member state has objections, particularly in relation to potential serious risk to public health, which cannot be resolved within the procedure scope and timelines, they will be referred to the coordination group for MR and DCPs and reviewed in a 60-day procedure. If this 60-day procedure does not result in a consensus by all member states, the product can be marketed in the countries whose health authorities agree that the product can be licensed. The issue raised will then enter a second referral procedure.

As with the MR procedure, the advantage of the DCP is that the pharmaceutical company receives identical marketing authorizations for its medicinal product in all the member states of the EU in which it wants to market the product. This leads to considerable streamlining of all regulatory activities in regard to the product. Variations, line extensions, renewals, etc. are also handled in a coordinated manner with the RMS leading the activity.

Once a DCP has been completed, the pharmaceutical company can subsequently apply for marketing authorizations for the medicinal product in additional EU member states by means of the MR procedure.

All products, whether centrally authorized or authorized by the MR or DCP, may only be sold in other member states if the product information is in the official language of the state in which the product will be sold, which effectively requires specific packaging and labeling of the product.

Under the national procedure, a company applies for a marketing authorization in one member state. The national procedure can now only be used if the pharmaceutical company does not seek authorization in more than one member state. If it does seek wider marketing authorizations, it must use the MR or DCP.

Before a generic pharmaceutical product can be marketed in the EU, a marketing authorization must be obtained. If a generic pharmaceutical product is shown to be essentially the same as, or bioequivalent to, one that is already on the market and which has been authorized in the EU for a specified number of years, as explained in the section on data exclusivity below, no further preclinical or clinical trials are required for that new generic pharmaceutical product to be authorized. The generic applicant can file an abridged application for marketing authorization, but in order to take advantage of the abridged procedure, the generic manufacturer must demonstrate specific similarities, including bioequivalence, to the already authorized product. Access to clinical data of the reference drug is governed by the European laws relating to data exclusivity, which are outlined below. Other products, such as new dosages of established products, must be subjected to further testing, and “bridging data” in respect of these further tests must be

submitted along with the abridged application.

An applicant for a generic marketing authorization currently cannot avail itself of the abridged procedure in the EU by relying on the originator pharmaceutical company's data until expiry of the relevant period of exclusivity given to that data. For products first authorized prior to October 30, 2005, this period is six or ten years (depending on the member state in question and/or the regulatory procedure used by the originator) after the grant of the first marketing authorization sought for the relevant product, due to data exclusivity provisions which have been in place. From October 30, 2005, the implementation of a new EU directive (2004/27/EC) harmonized the data exclusivity period for originator pharmaceutical products throughout the EU member states, which were legally obliged to have implemented the directive by October 30, 2005. The new regime for data exclusivity provides for an eight-year data exclusivity period commencing from the grant of first marketing authorization. After the eight-year period has expired, a generic applicant can refer to the data of the originator pharmaceutical company in order to file an abridged application for approval of its generic equivalent product. Yet, conducting the necessary studies and trials for an abridged application, within the data exclusivity period, is not regarded as contrary to patent rights or to

supplementary protection certificates for medicinal products. However, the applicant will not be able to launch its product for an additional two years. This ten-year total period may be extended to 11 years if the original marketing authorization holder obtains, within those initial eight years, a further authorization for a new therapeutic use of the product which is shown to be of significant clinical benefit. Further, specific data exclusivity for one year may be obtained for a new indication for a well-established substance, provided that significant preclinical or clinical studies were carried out in relation to the new indication. This new regime for data exclusivity applies to products first authorized after October 30, 2005.

In addition to obtaining approval for each product, in most EU countries the pharmaceutical product manufacturer's facilities must obtain approval from the national supervisory authority. The EU has a code of good manufacturing practice, with which the marketing authorization holder must comply. Regulatory authorities in the EU may conduct inspections of the manufacturing facilities to review procedures, operating systems and personnel qualifications.

In order to control expenditures on pharmaceuticals, most member states in the EU regulate the pricing and reimbursement of products and in some cases limit the range of different forms of drugs available for prescription by national health services. These controls can result in considerable price differences between member states. In addition, in past years, as part of overall programs to reduce health care costs, certain European governments have prohibited price increases and have introduced various systems designed to lower prices. Some European governments have also set minimum targets for generics prescribing.

Certain markets in which Mylan does business have recently undergone, some for the first time, or will soon undergo, government-imposed price reductions or similar pricing pressures on pharmaceutical products. In addition, a number of markets in which we operate have implemented or may implement tender, or tender-like, systems for generic pharmaceuticals in an effort to lower prices. Such measures are likely to have a negative impact on sales and gross profit in these markets. However, some pro-generic government initiatives in certain markets could help to offset some of this unfavorable effect by potentially increasing generic utilization.

Rest of World

Australia

The pharmaceutical industry is one of the most highly regulated industries in Australia. The Australian government is heavily involved in the operation of the industry, through the registration of medicines and licensing of manufacturing facilities, as well as subsidizing patient cost of most prescription medicines sold in Australia. The Australian government authority, the Therapeutic Goods Administration (the "TGA"), regulates the quality, safety and efficacy of therapeutic goods and is responsible for granting authorization to market pharmaceutical products in Australia and for inspecting and approving manufacturing facilities.

The TGA operates according to the Commonwealth of Australia's Therapeutic Goods Act 1989 (Cth) (the "Act"). Specifically the Act regulates the registration, listing, quality, safety, efficacy, promotion and sale of therapeutic goods, including pharmaceuticals, supplied in Australia. The TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard with a goal of ensuring that the Australian community has access within a reasonable time to therapeutic advances. Australian manufacturers of all medicines must be licensed under Part 3-3 of the Act and their manufacturing processes must comply with the principles of the good manufacturing practices in Australia. Similar standards and audits apply for both domestic and foreign manufactured products.

Generic medicines are subject to an abbreviated review process by the TGA, if the product can demonstrate essential similarity to the originator brand. Essential similarity means the same active ingredient in the same dose form, delivering the active ingredient to the patient at the same rate and extent, compared to the original brand. If proven, safety and efficacy is assumed to be the same.

All therapeutic goods manufactured for supply in Australia must be listed or registered in the Australian Register of Therapeutic Goods (the “ARTG”), before they can be promoted or supplied for use and/or sale in Australia. The ARTG is a database kept for the purpose of compiling information in relation to therapeutic goods for use in humans and lists therapeutic goods which are approved for supply in Australia.

Medicines assessed as having a higher level of risk must be registered, while those with a lower level of risk can be listed. The majority of listed medicines are self-selected by consumers and used for self-treatment. In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used are taken into account.

Labeling, packaging and advertising of pharmaceutical products are also regulated by the Act and other relevant statutes including fair trading laws and pharmaceutical industry codes.

Australia has a five-year data exclusivity period, whereby any data relating to a pharmaceutical product cannot be referred to or used in the examination by the TGA of another company's dossier, until five years after the original product was approved.

The Pharmaceutical Benefits Scheme (the "PBS"), which has been in place since 1948, subsidizes the cost to consumers of medicines listed on the PBS, if the medicines have demonstrated acceptable clinical need, cost and effectiveness. The goal of the PBS is to make medicines available at the lowest cost compatible with reliable supply and to base access on medical need rather than ability to pay.

The government exerts a significant degree of control over the pharmaceuticals market through the PBS. More than 80% of all prescription medicine sold in Australia is reimbursed by the PBS. The PBS is operated under the Commonwealth of Australia's National Health Act 1953. This statute governs matters such as who may sell pharmaceutical products, the prices at which pharmaceutical products may be sold to consumers and the prices government pays manufacturers, wholesalers and pharmacists for subsidized medicines.

If a new medicine is to be considered for listing on the PBS, the price is determined through a full health economic analysis submitted to the government's advisory committee, the Pharmaceutical Benefits Advisory Committee (the "PBAC"), based on incremental benefit to health outcome. If the incremental benefit justifies the price requested, the PBAC then makes a recommendation to the government to consider listing the product on the PBS. In May 2014, as part of a government reform program in Australia, the Pharmaceutical Benefits Pricing Authority was abolished and the Minister for Health ("Minister"), or delegate, considers pricing matters for approximately five to six weeks following PBAC meetings. Factors contributing to pricing decisions include items such as information on the claims made in a submission, advice from the PBAC, information about the proposed price, the price and use of comparative medicines and the cost of producing the medicine although with additional associated costs. The Minister may recommend that the proposed price is accepted; further negotiations take place for a lower price or prices within a specific range; or for some products, risk sharing arrangements to be developed and agreed upon. The Australian government's purchasing power is used to obtain lower prices as a means of controlling the cost of the program. The PBS also stipulates the wholesaler margin for drugs listed on the PBS. Wholesalers therefore have little pricing power over the majority of their product range and as a result are unable to increase profitability by increasing prices.

Following entry of the first generic products onto the market, the PBS price reimbursed to pharmacies decreases by 16% for both the originator product and generic products with a brand equivalence indicator permitting substitution at the pharmacy level. Thereafter, both the originator and generic suppliers are required to disclose pricing information relating to the sale of medicines to the Price Disclosure Data Administrator, and twelve months (up until October 2014, it was 18 months) after initial generic entry, there is a further PBS price reduction based on the weighted average disclosed price if the weighted average disclosed price is 10% or more below the existing PBS price. Ongoing price disclosure cycles and calculation of the weighted average disclosed price occur every six months, and further reductions are made to the PBS price whenever the weighted average disclosed price is 10% or more below the existing PBS price. The price disclosure system has had, and will continue to have for several years beyond 2014, a negative impact on sales and gross profit in this market.

Japan

In Japan, we are governed by various laws and regulations, including the Pharmaceutical Affairs Law (Law No. 145, 1960), as amended by the Pharmaceuticals and Medical Devices Law ("PMDL"), and the Products Liability Law (Law No. 85, 1994). The PMDL was amended in November 2014 to establish a fast-track authorization process for

regenerative medicine products, restructure medical device regulation and establish reporting obligations for package inserts for drugs and medical devices. Regenerative medicine products are newly defined under the amended PMDL as a product for medical use in humans to reconstruct, restore, or form the structure or function of a human body, in which cells of humans are cultured or otherwise processed.

Under the amended PMDL, there are two routes to obtain authorization to manufacture and market a medicine product. The first route is the standard authorization system for drugs in which the efficacy and safety of the product must be shown in order to obtain authorization. The standard authorization procedure may take a significant amount of time to launch a regenerative medicine product because the quality of regenerative medicine products is heterogeneous by nature and therefore it is difficult to collect the data necessary to evaluate and demonstrate the efficacy. As such, the amended PMDL instituted the second route as follows: if the regenerative medicine product is heterogeneous, the efficacy of the regenerative medicine

product is assumed. Thus, if the safety of the regenerative medicine product is demonstrated through clinical trials, the Minister of the Ministry of Health, Labor and Welfare (“MHLW”) may authorize the applicant to manufacture and market the regenerative medicine product with certain conditions for a fixed term after receiving an expert opinion from the Pharmaceutical Affairs and Food Sanitation Council.

The amended PMDL also restructured medical device regulations including expanding the scope for certification in accordance with the classifications agreed upon by the Global Harmonization Task Force, new regulations on medical device software in which software may be authorized as a medical device independent of the medical device hardware into which it is incorporated, system change for medical device manufacturing so that a company may manufacture a medical device when the company registers such medical device and streamlined Quality Management Service Inspection such that the inspection is performed for each category of medical products.

In addition, under the amended PMDL, the holder of a business license for the manufacture and marketing of regenerative medicine products or medical devices must notify the MHLW of the contents of the package insert, including any cautionary statements necessary to use and deal with the products, before it manufactures and markets them. The license holder must also publish the contents of the package inserts on the website of the Pharmaceuticals and Medical Devices Agency.

Under the amended PMDL, the retailing or supply of a pharmaceutical that a person has manufactured (including manufacturing under license) or imported is defined as “marketing,” and in order to market pharmaceuticals, one has to obtain a license, which we refer to herein as a Marketing License, from the MHLW. The authority to grant the “Marketing License,” is delegated to prefectural governors; therefore, the relevant application must be filed with the relevant prefectural governor. A Marketing License will not be granted if the quality control system for the pharmaceutical for which the Marketing License has been applied or the post-marketing safety management system for the relevant pharmaceutical does not comply with the standards specified by the relevant Ministerial Ordinance made under the Pharmaceutical Affairs Law.

In addition to the Marketing License, a person intending to market a pharmaceutical must, for each product, obtain marketing approval from the MHLW with respect to such marketing, which we refer to herein as “Marketing Approval.” Marketing Approval is granted subject to examination of the name, ingredients, quantities, structure, administration and dosage, method of use, indications and effects, performance and adverse reactions, and the quality, efficacy and safety of the pharmaceutical. A person intending to obtain Marketing Approval must attach materials, such as data related to the results of clinical trials (including a bioequivalence study, in the case of generic pharmaceuticals) or conditions of usage in foreign countries. Japan provides for market exclusivity through a re-examination system, which prevents the entry of generic pharmaceuticals until the end of the re-examination period, which can be up to eight years, and ten years in the case of drugs used to treat rare diseases (“orphan drugs”).

The authority to grant Marketing Approval in relation to pharmaceuticals for certain specified purposes (e.g., cold medicines and decongestants) is delegated to the prefectural governors by the MHLW, and applications in relation to such pharmaceuticals must be filed with the governor of the relevant prefecture where the relevant company’s head office is located. Applications for pharmaceuticals for which the authority to grant the Marketing Approval remains with the MHLW must be filed with the Pharmaceuticals and Medical Devices Agency. When an application is submitted for a pharmaceutical whose active ingredients, quantities, administration and dosage, method of use, indications and effects are distinctly different from those of pharmaceuticals which have already been approved, the MHLW must seek the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

The amended PMDL provides that when (a) the pharmaceutical that is the subject of an application is shown not to result in the indicated effects or performance indicated in the application, (b) the pharmaceutical is found to have no value as a pharmaceutical because it has harmful effects outweighing its indicated effects or performance, or (c) in

addition to (a) and (b) above, when the pharmaceutical falls within the category designated by the relevant Ministerial Ordinance as not being appropriate as a pharmaceutical, Marketing Approval shall not be granted.

The MHLW must cancel a Marketing Approval, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council, when the MHLW finds that the relevant pharmaceutical falls under any of (a) through (c) above. In addition, the MHLW can order the amendment of a Marketing Approval when it is necessary to do so from the viewpoint of public health and hygiene. Moreover, the MHLW can order the cancellation or amendment of a Marketing Approval when (1) the necessary materials for re-examination or re-evaluation, which the MHLW has ordered considering the character of pharmaceuticals, have not been submitted, false materials have been submitted or the materials submitted do not comply with the criteria specified by the MHLW, (2) the relevant company's Marketing License has expired or has been canceled (a Marketing License needs to be renewed every five years), (3) the regulations regarding investigations of facilities in relation to manufacturing management standards or quality control have been violated, (4) the conditions set in relation to the Marketing

Approval have been violated, or (5) the relevant pharmaceutical has not been marketed for three consecutive years without a due reason.

Doctors and pharmacists providing medical services pursuant to national health insurance are prohibited from using pharmaceuticals other than those specified by the MHLW. The MHLW also specifies the standards of pharmaceutical prices, which we refer to herein as Drug Price Standards. The Drug Price Standards are used as the basis of the calculation of the price paid by medical insurance for pharmaceuticals. The governmental policy relating to medical services and the health insurance system, as well as the Drug Price Standards, is revised every two years.

Brazil

In Brazil, pharmaceutical manufacturers and products are regulated by the National Agency of Sanitary Surveillance (“ANVISA”). ANVISA is a governmental body directly linked to the Ministry of Health, responsible for promoting the protection of the health of the population through the sanitary control of production, storage, distribution, importation and marketing of products and services subject to sanitary surveillance. ANVISA is responsible for registering drugs and supervising quality control, as well as issuing licenses to companies for the manufacturing, handling, packaging, distribution, advertising, importation and exportation of pharmaceutical products.

API

The primary regulatory oversight of API manufacturers is through inspection of the manufacturing facility in which APIs are produced, as well as the manufacturing processes and standards employed in the facility. The regulatory process by which API manufacturers generally register their products for commercial sale in the U.S. and other similarly regulated countries is via the filing of a DMF. DMFs are confidential documents containing information on the manufacturing facility and processes used in the manufacture, characterization, quality control, packaging and storage of an API. The DMF is reviewed for completeness by the FDA, or other similar regulatory agencies in other countries, in conjunction with applications filed by FDF manufacturers, requesting approval to use the given API in the production of their drug products.

Specialty Segment

The process required by the FDA before a pharmaceutical product with active ingredients that have not been previously approved may be marketed in the U.S. generally involves the following:

- laboratory and preclinical tests;
- submission of an Investigational New Drug (“IND”) application, which must become effective before clinical studies may begin;
- adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;
- submission of an NDA containing the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing matters such as manufacturing and quality assurance;
- scale-up to commercial manufacturing; and
- FDA approval of an NDA.

Preclinical tests include laboratory evaluation of the product and its chemistry, formulation and stability, as well as toxicology and pharmacology studies to help define the pharmacological profile of the drug and assess the potential safety and efficacy of the product. The results of these studies are submitted to the FDA as part of the IND. They must demonstrate that the product delivers sufficient quantities of the drug to the bloodstream or intended site of action to produce the desired therapeutic results before human clinical trials may begin. These studies must also provide the appropriate supportive safety information necessary for the FDA to determine whether the clinical studies proposed to be conducted under the IND can safely proceed. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, during that 30-day period, raises concerns or questions about the conduct of the proposed trials,

as outlined in the IND. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. In addition, an independent institutional review board must review and approve any clinical study prior to initiation.

Human clinical studies are typically conducted in three sequential phases, which may overlap:

Phase I – The drug is initially introduced into a relatively small number of healthy human subjects or patients and is tested for safety, dosage tolerance, mechanism of action, absorption, metabolism, distribution and excretion.

Phase II – Studies are performed with a limited patient population to identify possible adverse effects and safety risks, to assess the efficacy of the product for specific targeted diseases or conditions, and to determine dosage tolerance and optimal dosage.

Phase III – When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to evaluate further dosage and clinical efficacy and to test further for safety in an expanded patient population at geographically dispersed clinical study sites.

The results of the product development, preclinical studies and clinical studies are then submitted to the FDA as part of the NDA. The NDA drug development and approval process could take from three to more than ten years.

Research and Development

R&D efforts are conducted on a global basis, primarily to enable us to develop, manufacture and market approved pharmaceutical products in accordance with applicable government regulations. Through various acquisitions, we have significantly bolstered our global R&D capabilities over the past several years, particularly in injectables and respiratory therapies. In the U.S., our largest market, the FDA is the principal regulatory body with respect to pharmaceutical products. Each of our other markets has separate pharmaceutical regulatory bodies, including, but not limited to, the Agence Nationale de Securite du Medicament et de Sante in France, Health Canada, the Medicines and Healthcare products Regulatory Agency in the U.K., the EMA (a decentralized body of the EU), the Bundesinstitut für Arzneimittel und Medizinprodukte in Germany, the Irish Medicines Board in Ireland, the Agenzia Italiana del Farmaco in Italy, the Agencia Española de Medicamentos y Productos Sanitarios in Spain, the TGA in Australia, the MHLW in Japan, Drug Controller General of India, ANVISA in Brazil and the World Health Organization (“WHO”), the regulatory body of the United Nations.

Our global R&D strategy emphasizes the following areas:

- development of both branded and generic finished dose products for the global marketplace, including ARV programs;
- development of pharmaceutical products that are technically difficult to formulate or manufacture because of either unusual factors that affect their stability or bioequivalence or unusually stringent regulatory requirements;
- development of novel controlled-release technologies and the application of these technologies to reference products;
- development of drugs that target smaller, specialized or underserved markets;
- development of generic drugs that represent first-to-file opportunities in the U.S. market;
- expansion of the existing oral solid dosage product portfolio, including with respect to additional dosage strengths;
- development of injectable products;
- development of unit dose oral inhalation products for nebulization;
- development of APIs;
- development of compounds using a dry powder inhaler and/or metered-dose inhaler for the treatment of asthma, COPD and other respiratory therapies;
- development of monoclonal anti-bodies (“biologics”);
- completion of additional preclinical and clinical studies for approved NDA products required by the FDA, known as post-approval (Phase IV) commitments; and
- conduct life-cycle management studies intended to further define the profile of products subject to pending or approved NDAs.

The success of generic biologics in the marketplace and our ability to be successful in this emerging market will depend on the implementation of balanced scientific standards for approval, while not imposing excessive clinical testing

demands or other hurdles for well-established products. Furthermore, an efficient patent resolution mechanism and a well-defined mechanism to grant interchangeability after the establishment of biosimilarity with the reference biological product will be key elements determining our future success in this area.

We have a robust generic pipeline. As of December 31, 2014, we had approximately 3,300 country level product approvals pending. During 2014, we completed 767 global country level product submissions, which included 64 in North America, 510 in Europe and 193 in Rest of World. These submissions included those for existing products in new markets as well as products new to the Mylan portfolio.

During the year ended December 31, 2014, we received 513 product approvals globally, including individual country level approvals. Of that total, there were 101 approvals in North America, including 65 in the U.S., 239 approvals in Europe and 173 approvals in Rest of World, of which 42 approvals were for ARV products. The 42 country level ARV approvals received consisted of 14 products in 13 different countries, with seven ARV approvals in the U.S. based upon the U.S. President's Emergency Plan for AIDS Relief. The 65 approvals in the U.S. consisted of 54 final ANDA approvals and 11 tentative ANDA approvals. The 239 approvals in Europe covered 80 different products resulting in a total of 639 product marketing licenses. The 173 approvals in Rest of World included 131 approvals from emerging markets which represented 41 products in 24 countries.

As of December 31, 2014, we had 283 ANDAs pending FDA approval, representing approximately \$111.3 billion in annual sales for the brand name equivalents of these products for the year ended December 31, 2014. Of those pending product applications, 44 were first-to-file Paragraph IV ANDA patent challenges, representing approximately \$29.3 billion in annual brand sales for the year ended December 31, 2014. The historic branded drug sales are not indicative of future generic sales, but are included to illustrate the size of the branded product market. Our R&D spending was \$582 million, \$508 million and \$401 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Patents, Trademarks and Licenses

We own or license a number of patents in the U.S. and other countries covering certain products and have also developed brand names and trademarks for other products. Generally, the brand pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks and license rights to be of significant value and act to protect these rights from infringement. However, our business is not dependent upon any single patent, trademark or license.

In the branded pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection.

An innovator product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovator is entitled.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to lawfully exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its

scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity is also sometimes influenced by regulatory intellectual property rights. Many developed countries provide certain non-patent incentives for the development of medicines. For example, the U.S., the EU and Japan each provide for a minimum period of time after the approval of a new drug during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy. Regulatory intellectual property rights are also available in certain markets as incentives for research on new indications, on orphan drugs and on medicines useful in treating pediatric patients. Regulatory intellectual property rights are independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a competitor from gaining regulatory

approval prior to the expiration of regulatory data exclusivity on the basis of the competitor’s own safety and efficacy data on its drug, even when that drug is identical to that marketed by the innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict the length of market exclusivity for any of our branded products with certainty because of the complex interaction between patent and regulatory forms of exclusivity and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

In addition to patents and regulatory forms of exclusivity, we also market products with trademarks. Trademarks have no effect on market exclusivity for a product, but are considered to have marketing value. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely.

Customers and Marketing

Generics Segment

In North America, we market products directly to wholesalers, distributors, retail pharmacy chains, long-term care facilities, mail order pharmacies and GPOs. We also market our generic products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, pharmacy benefit management companies and government entities. These customers, called “indirect customers,” purchase our products primarily through our wholesale customers. In North America, wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation, which may result in these groups gaining additional purchasing leverage.

In Europe and Rest of World, generic pharmaceuticals are sold to wholesalers, independent pharmacies and, in certain countries, directly to hospitals. Through a broad network of sales representatives, we adapt our marketing strategy to the different markets as dictated by their respective regulatory and competitive landscapes. Our API are sold primarily to generic FDF manufacturers throughout the world, as well as to other Mylan subsidiaries.

Specialty Segment

Mylan Specialty markets its products to a number of different customer audiences in the U.S., including health care practitioners, wholesalers, pharmacists and pharmacy chains, hospitals, payers, pharmacy benefit manager, health maintenance organizations (“HMOs”), home health care, long-term care and patients. We reach these customers through our field-based sales force and National Accounts team of approximately 370 employees, to increase our customers’ understanding of the unique clinical characteristics and benefits of our branded products. Additionally, Mylan Specialty supports educational programs to consumers and patients.

Major Customers

The following table represents the percentage of consolidated third party net sales to Mylan’s major customers during 2014, 2013 and 2012.

	Percentage of Third Party Net Sales			
	2014	2013	2012	
McKesson Corporation	19	% 14	% 13	%
AmeriSourceBergen Corporation	13	% 10	% 7	%
Cardinal Health, Inc.	12	% 15	% 14	%

Consistent with industry practice, we have a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. See the Application of Critical Accounting Policies section of our “Management’s Discussion and Analysis of Results of Operations and Financial Condition” for a discussion of our more significant revenue recognition provisions.

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:

United States. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

The U.S. pharmaceutical market is undergoing, and is expected to continue to undergo, rapid and significant technological changes, and we expect competition to intensify as technological advances are made. We intend to compete in this marketplace by (1) developing therapeutic equivalents to branded products that offer unique marketing opportunities, are difficult to formulate and/or have significant market size, (2) developing or licensing brand pharmaceutical products that are either patented or proprietary and (3) developing or licensing pharmaceutical products that are primarily for indications having relatively large patient populations or that have limited or inadequate treatments available, among other strategies.

Our sales can be impacted by new studies that indicate that a competitor's product has greater efficacy for treating a disease or particular form of a disease than one of our products. Sales on some of our products can also be impacted by additional labeling requirements relating to safety or convenience that may be imposed on our products by the FDA or by similar regulatory agencies. If competitors introduce new products and processes with therapeutic or cost advantages, our products can be subject to progressive price reductions and/or decreased volume of sales.

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages effective January 1, 2010. The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed non-innovator products, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed innovator or single-source products require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

Under Part D of the Medicare Modernization Act, Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. As a result, usage of pharmaceuticals has increased, which is a trend that we believe will continue to benefit the generic pharmaceutical industry. However, such potential sales increases may be offset by increased pricing pressures, due to the enhanced purchasing power of the private sector providers that are negotiating on behalf of Medicare beneficiaries.

Canada. Canada is a well-established generics market characterized by a number of local and multi-national competitors. The individual Canadian provinces control pharmaceutical pricing and reimbursement. A number of Canada's

provinces are moving towards a tender system, which has and may continue to negatively affect the pricing of pharmaceutical products.

France. Generic penetration in France is relatively low compared to other large pharmaceutical markets, with low prices resulting from government initiatives. As pharmacists are the primary customers in this market, established relationships, driven by breadth of portfolio and effective supply chain management, are key competitive advantages.

Italy. The Italian generic market is relatively small due to few incentives for market stakeholders and in part to low prices on available brand name drugs. Also to be considered is the fact that the generic market in Italy suffered a certain delay compared to other European countries due to extended patent protection. The Italian government has put forth only limited measures aimed at increasing generic usage, and as such generic substitution is still in its early stages. Pharmacists will play a key role in future market expansion, due to higher margins provided by generic versus branded products.

United Kingdom. The U.K. is one of the most competitive markets, with low barriers to entry and a high degree of fragmentation. Competition among manufacturers, along with indirect control of pricing by the government, has led to strong downward pricing pressure. Companies in the U.K. will continue to compete on price, with consistent supply chain and breadth of product portfolio also coming into play.

Spain. Spain is a rapidly growing, highly fragmented generic market with many participants. As a result of recent legislative changes, all regions within Spain will move to INN prescribing and substitution, thus making the pharmacists the key driver of generic usage. Within the last two years, the Andalusia region, representing 20% of the total market, has evolved into a tendering commercial model. However, it is currently anticipated that this move could be gradually reversed due to Central Government opposition. Companies compete in Spain based on being first to market, offering a wide portfolio, building strong relationships with customers and providing a consistent supply of quality products.

The Netherlands. The Netherlands market has become highly competitive as a result of a large number of generic players, one of the highest generic penetration rates in Europe and the continued use of a tender system. Under a tender system, health insurers are entitled to issue invitations to tender products. Pricing pressures resulting from an effort to win the tender should drive near-term competition. Mylan is able to play a significant role in tenders but also has strong non-tendered sales which provides further opportunities for growth.

Germany. The German market has become highly competitive as a result of a large number of generic players, one of the highest generic penetration rates in Europe, and the continued use of a tender system. Pricing pressures resulting from an effort to win the tender should drive near-term competition.

Poland. Poland is a mature and well-established generics market characterized by a high level of generic penetration in comparison to other large European pharmaceutical markets. Generic substitution is permitted, but not obligatory and pricing is indirectly controlled by the government. There are a large number of local and multi-national competitors within the market.

India. Intense competition by other API suppliers in the Indian pharmaceuticals market has, in recent years, led to increased pressure on prices. We expect that the exports of API and generic FDF products from India to developed markets will continue to increase. The success of Indian pharmaceutical companies is attributable to established development expertise in chemical synthesis and process engineering, development of FDF, availability of highly skilled labor and the low cost manufacturing base.

The Indian commercial market is a rapidly growing, highly fragmented generic market with a significant number of participants. Companies compete in India based on price, product portfolio and the ability to provide a consistent supply of quality products.

Australia. The Australian generic market is small by international standards, in terms of prescriptions, value and the number of active participants. Patent extensions that delayed patent expiration are somewhat responsible for under-penetration of generic products.

Japan. Historically, government initiatives have kept all drug prices low, resulting in little incentive for generic usage. More recent pro-generic actions by the government should lead to growth in the generics market, in which doctors, pharmacists and hospital purchasers will all play a key role.

Brazil. The Brazilian pharmaceutical market is the largest in South America. Since the entry in force of generic drug laws in Brazil, the generic segment of the pharmaceutical market has grown rapidly. The industry is highly competitive with a broad presence of multinational and national competitors.

Product Liability

Global product liability litigation represents an inherent risk to firms in the pharmaceutical industry. We utilize a combination of self-insurance (including through our wholly owned captive insurance subsidiary) and traditional third-party insurance policies with regard to our product liability claims. Such insurance coverage at any given time reflects market conditions, including cost and availability, existing at the time the policy is written and the decision to obtain commercial insurance coverage or to self-insure varies accordingly.

Raw Materials

Mylan utilizes a global approach to managing relationships with its suppliers. The APIs and other materials and supplies used in our pharmaceutical manufacturing operations are generally available and purchased from many different U.S. and non-U.S. suppliers, including Mylan India. However, in some cases, the raw materials used to manufacture pharmaceutical products are available only from a single supplier. Even when more than one supplier exists, we may choose, and in some cases have chosen, only to list one supplier in our applications submitted to the FDA. Any change in a supplier not previously approved must then be submitted through a formal approval process with the FDA.

Seasonality

Certain parts of our business are affected by seasonality, primarily the Specialty segment and Rest of World within our Generics segment. The seasonal impact of these particular businesses may affect a quarterly comparison within any fiscal year; however, this impact is generally not material to our annual consolidated results.

Environment

We strive to comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our operations or competitive position.

Employees

As of December 31, 2014, Mylan's global workforce included more than 25,000 employees and external contractors. With the completion of the Transaction, Mylan N.V. has increased its workforce to approximately 30,000 employees and external contractors. Certain production and maintenance employees at our manufacturing facility in Morgantown, West Virginia, are represented by the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union and its Local Union 8-957 AFL-CIO under a contract that expires on April 21, 2017. In addition, there are non-U.S. Mylan locations that have employees who are unionized or part of works councils or trade unions.

Securities Exchange Act Reports

Unless otherwise indicated, the following discussion relates to Mylan Inc. prior to the consummation of the Transaction which occurred on February 27, 2015. New Mylan maintains an Internet website at the following address: mylan.com. New Mylan, which is the successor registrant to Mylan as discussed in the Explanatory Note, makes available on or through its Internet website certain reports and amendments to those reports that both Mylan and New Mylan file with the Securities and Exchange Commission ("SEC") in accordance with the Securities Exchange Act of 1934. These include annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. New Mylan makes this information available on its website free of charge, as soon as reasonably practicable after electronically filed with, or furnished to, the SEC. The contents of New Mylan's website are not incorporated by

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reference in this Report on Form 10-K and shall not be deemed “filed” under the Securities Exchange Act of 1934.

The public may also read and copy any materials that we or New Mylan file with the SEC at the SEC’s Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information about the Public Reference Room by contacting the SEC at 1.800.SEC.0330. Reports filed with the SEC are also made available on the SEC website (www.sec.gov).

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ITEM 1A. Risk Factors

We operate in a complex and rapidly changing environment that involves risks, many of which are beyond our control. Any of the following risks, if they occur, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price. These risks should be read in conjunction with the other information in this Annual Report on Form 10-K. As described in the Explanatory Note above, this Form 10-K is a Mylan Inc. filing. However, the risks described below also apply to New Mylan. Additional risks that may affect New Mylan are described in the Registration Statement on Form S-4 filed by New Mylan with the SEC on November 5, 2014, as amended on December 9 and December 23, 2014.

CURRENT AND CHANGING ECONOMIC CONDITIONS MAY ADVERSELY AFFECT OUR INDUSTRY, BUSINESS, PARTNERS AND SUPPLIERS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR SHARE PRICE.

The global economy continues to experience significant volatility, and the economic environment may continue to be, or become, less favorable than that of past years. Among other matters, the continued risk of a debt default by one or more European countries, related financial restructuring efforts in Europe, and/or evolving deficit and spending reduction programs instituted by the U.S. and other governments could negatively impact the global economy and/or the pharmaceutical industry. This has led, and/or could lead, to reduced consumer and customer spending and/or reduced or eliminated governmental or third party payor coverage or reimbursement in the foreseeable future, and this may include spending on health care, including but not limited to pharmaceutical products. While generic drugs present an alternative to higher-priced branded products, our sales could be negatively impacted if patients forego obtaining health care, patients and customers reduce spending or purchases, and/or if governments and/or third-party payors reduce or eliminate coverage or reimbursement amounts for pharmaceuticals and/or impose price or other controls adversely impacting the price or availability of pharmaceuticals. In addition, reduced consumer and customer spending, and/or reduced government and/or third party payor coverage or reimbursement, and/or new government controls, may drive us and our competitors to decrease prices and/or may reduce the ability of customers to pay and/or may result in reduced demand for our products. The occurrence of any of these risks could have a material adverse effect on our industry, business, financial condition, results of operations, cash flows, and/or share price.

OUR BUSINESS, FINANCIAL CONDITION, AND RESULTS OF OPERATIONS ARE SUBJECT TO RISKS ARISING FROM THE INTERNATIONAL SCOPE OF OUR OPERATIONS.

Our operations extend to numerous countries outside the U.S. and are subject to the risks inherent in conducting business globally and under the laws, regulations, and customs of various jurisdictions. These risks include, but are not limited to:

- compliance with a variety of national and local laws of countries in which we do business, including but not limited to restrictions on the import and export of certain intermediates, drugs, and technologies;
- compliance with a variety of U.S. laws including, but not limited to, the Iran Threat Reduction and Syria Human Rights Act of 2012; and rules relating to the use of certain “conflict minerals” under Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act;
- changes in laws, regulations, and practices affecting the pharmaceutical industry and the health care system, including but not limited to imports, exports, manufacturing, quality, cost, pricing, reimbursement, approval, inspection, and delivery of health care;
- fluctuations in exchange rates for transactions conducted in currencies other than the functional currency;
- adverse changes in the economies in which we or our partners and suppliers operate as a result of a slowdown in overall growth, a change in government or economic policies, or financial, political, or social change or instability in such countries that affects the markets in which we operate, particularly emerging markets;
- differing local product preferences and product requirements;
- changes in employment laws, wage increases, or rising inflation in the countries in which we or our partners and suppliers operate;

- supply disruptions, and increases in energy and transportation costs;
- natural disasters, including droughts, floods, and earthquakes in the countries in which we operate;
- local disturbances, terrorist attacks, riots, social disruption, or regional hostilities in the countries in which we or our partners and suppliers operate; and
- government uncertainty, including as a result of new or changed laws and regulations.

We also face the risk that some of our competitors have more experience with operations in such countries or with international operations generally and may be able to manage unexpected crises more easily. Furthermore, whether due to language, cultural or other differences, public and other statements that we make may be misinterpreted, misconstrued, or taken out of context in different jurisdictions. Moreover, the internal political stability of, or the relationship between, any country or countries where we conduct business operations may deteriorate. Changes in a country's political stability or the state of relations between any such countries are difficult to predict and could adversely affect our operations. Any such changes could lead to a decline in our profitability and/or adversely impact our ability to do business. Any meaningful deterioration of the political or social stability in and/or diplomatic relations between any countries in which we or our partners and suppliers do business could have a material adverse effect on our operations. The occurrence of any of the above risks could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

OUR SIGNIFICANT OPERATIONS IN INDIA MAY BE ADVERSELY AFFECTED BY REGULATORY, ECONOMIC, SOCIAL, AND POLITICAL UNCERTAINTIES OR CHANGE, MAJOR HOSTILITIES, MILITARY ACTIVITY, AND/OR ACTS OF TERRORISM IN SOUTHERN ASIA.

In recent years, our Indian subsidiaries have benefited from many policies of the Government of India and the Indian state governments in which they operate, which are designed to promote foreign investment generally, including significant tax incentives, liberalized import and export duties, and preferential rules on foreign investment and repatriation. There is no assurance that such policies will continue. Various factors, such as changes in the current federal government, could trigger significant changes in India's economic liberalization and deregulation policies and disrupt business and economic conditions in India generally and our business in particular.

In addition, our financial performance may be adversely affected by general economic conditions; economic, fiscal and social policy in India, including changes in exchange rates and controls, interest rates and taxation policies; and social instability and political, economic, or diplomatic developments affecting India in the future. In particular, India has experienced significant economic growth over the last several years, but faces major challenges in sustaining that growth in the years ahead. These challenges include the need for substantial infrastructure development and improving access to health care and education. Our ability to recruit, train, and retain qualified employees and develop and operate our manufacturing facilities in India could be adversely affected if India does not successfully meet these challenges.

Southern Asia has, from time to time, experienced instances of civil unrest and hostilities among neighboring countries, including India and Pakistan, and within the countries themselves. Rioting, military activity, or terrorist attacks in the future could influence the Indian economy and our operations and employees by disrupting operations and communications and making travel and the conduct of our business more difficult. Resulting political or social tensions could create a greater perception that investments in companies with Indian operations involve a high degree of risk, and that there is a risk of disruption of services provided by companies with Indian operations, which could impact our customers' willingness to do business with us and have a material adverse effect on the market for our products. Furthermore, if India were to become engaged in armed hostilities, including but not limited to hostilities that were protracted or involved the threat or use of nuclear or other weapons of mass destruction, our India operations, including our recently acquired Agila operations in India, might not be able to continue. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. The occurrence of any of these risks could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THE TRANSACTION MAY NOT ACHIEVE THE INTENDED BENEFITS OR MAY DISRUPT NEW MYLAN'S PLANS AND OPERATIONS.

There can be no assurance that New Mylan will be able to successfully integrate the Business with the business of Mylan or otherwise realize the expected benefits of the Transaction. New Mylan's ability to realize the anticipated benefits of the Transaction will depend, to a large extent, on its ability to integrate the Business with the business of Mylan and realize the

benefits of the combined business. The combination of two independent businesses is a complex, costly, and time-consuming process. New Mylan's business may be negatively impacted following the Transaction if it is unable to effectively manage its expanded operations. The integration will require significant time and focus from management following the Transaction and may divert attention from the day-to-day operations of the combined business. Additionally, consummation of the Transaction could disrupt current plans and operations, which could delay the achievement of New Mylan's strategic objectives.

The expected synergies and operating efficiencies of the Transaction may not be fully realized, which could result in increased costs and have a material adverse effect on New Mylan's business, financial condition, results of operations, cash flows, and/or share price. In addition, the overall integration of the businesses may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management's attention, among other potential adverse consequences. The difficulties of combining the operations of the businesses include, among others:

• the diversion of management's attention to integration matters;

• difficulties in achieving anticipated synergies, operating efficiencies, business opportunities, and growth prospects from combining the Business with the pre-Transaction business of Mylan;

• difficulties in the integration of operations and systems, including enterprise resource planning systems;

• difficulties in the integration of employees;

• difficulties in managing the expanded operations of a significantly larger and more complex company;

• challenges in keeping existing customers and obtaining new customers;

• challenges in attracting and retaining key personnel; and

• the complexities of managing the ongoing relationship with Abbott, which will include agreements providing for transition services, manufacturing relationships, and license arrangements.

Many of these factors will be outside of New Mylan's control and any one of them could result in increased costs, decreases in the amount of expected revenues, and diversion of management's time and energy, which could have a material adverse effect on New Mylan's business, financial condition, results of operations, cash flows, and/or share price. In addition, even if the operations of Mylan and the Business are integrated successfully, New Mylan may not realize the full benefits of the Transaction, including the synergies, operating efficiencies, or sales or growth opportunities that are expected. These benefits may not be achieved within the anticipated time frame or at all. All of these factors could cause dilution to New Mylan's earnings per share, decrease or delay the expected accretive effect of the Transaction, and/or negatively impact the price of New Mylan's ordinary shares.

WE MAY NOT BE ABLE TO FULLY REALIZE THE ANTICIPATED BENEFITS OF THE AGILA ACQUISITION.

Our acquisition of Agila is subject to integration risks and costs and uncertainties associated with the operation of acquired businesses. The Agila acquisition involves the integration of Agila with our existing businesses. We have been, and will continue to be, required to devote significant management attention and resources to integrating Agila. We may also experience difficulties in combining corporate cultures. Delays or unexpected difficulties in the integration process could adversely affect our business, financial condition, results of operations, cash flows, and/or share price. Even if we are able to integrate Agila's operations successfully into our business, this integration may not result in the realization of the full benefits of synergies, cost savings and operational efficiencies that we expect to realize and these benefits may not be achieved within a reasonable period of time.

On September 9, 2013, prior to our completion of the Agila acquisition, the FDA issued a warning letter to Strides Arcolab for its Agila Sterile Manufacturing Facility 2 in Bangalore, India. This facility is one of Agila's eight FDA-approved sterile manufacturing facilities. We continue to work closely with the FDA to fully address its observations with respect to this facility and are working to resolve this matter expeditiously. No assurances can be provided that the resolution of the issues identified in the FDA's letter will not have a material adverse effect on our global injectables business. Failing to realize the anticipated benefits of the Agila acquisition and/or failing to resolve the issues identified in the FDA's letter could have a material adverse effect on our business, financial condition,

results of operations, cash flows, and/or share price.

AN INABILITY TO IDENTIFY OR SUCCESSFULLY BID FOR SUITABLE ACQUISITION TARGETS, OR CONSUMMATE AND EFFECTIVELY INTEGRATE RECENT AND FUTURE POTENTIAL ACQUISITIONS, COULD

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LIMIT OUR FUTURE GROWTH AND HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR SHARE PRICE.

We intend to continue to seek to expand our product line and/or business platform organically as well as through complementary or strategic acquisitions of other companies, products, or assets or through joint ventures, licensing agreements, or other arrangements. Acquisitions or similar arrangements may prove to be complex and time consuming and require substantial resources and effort. We may compete for certain acquisition targets with companies having greater financial resources than us or other advantages over us that may hinder or prevent us from acquiring a target or completing another transaction, which could also result in significant diversion of management time, as well as substantial out-of-pocket costs.

If an acquisition is consummated, the integration of such acquired business, product, or other assets into us may also be complex, time consuming, and result in substantial costs and risks. The integration process may distract management and/or disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, partners, suppliers, regulators, and others with whom we have business or other dealings. In addition, there are operational risks associated with the integration of acquired businesses. These risks include, but are not limited to, difficulties in achieving or inability to achieve identified or anticipated financial and operating synergies, cost savings, revenue synergies, and growth opportunities; difficulties in consolidating or inability to effectively consolidate information technology and manufacturing platforms, business applications, and corporate infrastructure; the impact of pre-existing legal and/or regulatory issues, such as quality and manufacturing concerns, among others; the risks that acquired companies do not operate to the same quality, manufacturing, or other standards as us; the impacts of substantial indebtedness and assumed liabilities; challenges associated with operating in new markets; and the unanticipated effects of export controls, exchange rate fluctuations, domestic and foreign political conditions, and/or domestic and foreign economic conditions.

We may be unable to realize synergies or other benefits, including tax savings, expected to result from acquisitions, joint ventures, or other transactions or investments we may undertake, or we may be unable to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits. Realization of the anticipated benefits of acquisitions or other transactions could take longer than expected, and implementation difficulties, unforeseen expenses, complications and delays, market factors, or deterioration in domestic and global economic conditions could reduce the anticipated benefits of any such transactions. We also may inherit legal, regulatory, and other risks that occurred prior to the acquisition, whether known or unknown to us.

Any one of these challenges or risks could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, require us to reexamine our business strategy, or otherwise cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

CHARGES TO EARNINGS RESULTING FROM ACQUISITIONS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS AND/OR SHARE PRICE.

Under accounting principles generally accepted in the United States of America (“U.S. GAAP”) business acquisition accounting standards, we recognize the identifiable assets acquired, the liabilities assumed, and any noncontrolling interests in acquired companies generally at their acquisition date fair values and, in each case, separately from goodwill. Goodwill as of the acquisition date is measured as the excess amount of consideration transferred, which is also generally measured at fair value, and the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Our estimates of fair value are based upon assumptions believed to be reasonable but which are inherently uncertain. After we complete an acquisition, the following factors could result in material charges and adversely affect our operating results and may adversely affect our cash flows:

• costs incurred to combine the operations of companies we acquire, such as transitional employee expenses and employee retention, redeployment or relocation expenses;

impairment of goodwill or intangible assets, including acquired in-process research and development (“IPR&D”);
amortization of intangible assets acquired;
a reduction in the useful lives of intangible assets acquired;

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identification of or changes to assumed contingent liabilities, including, but not limited to, contingent purchase price consideration, income tax contingencies and other non-income tax contingencies, after our final determination of the amounts for these contingencies or the conclusion of the measurement period (generally up to one year from the acquisition date), whichever comes first;

- charges to our operating results to eliminate certain duplicative pre-acquisition activities, to restructure our operations or to reduce our cost structure;
- charges to our operating results resulting from expenses incurred to effect the acquisition; and
- changes to contingent consideration liabilities, including accretion and fair value adjustments.

A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and earnings per share for the periods in which those costs are incurred. Such charges could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE HAVE GROWN AT A VERY RAPID PACE. OUR INABILITY TO EFFECTIVELY MANAGE OR SUPPORT THIS GROWTH MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR SHARE PRICE.

We have grown very rapidly over the past several years as a result of several acquisitions and increasing sales, and additional growth through acquisitions is possible in the future. This growth has put significant demands on our processes, systems, and people. We have made and expect to make further investments in additional personnel, systems, and internal control processes to help manage our growth. Attracting, retaining and motivating key employees in various departments and locations to support our growth are critical to our business, and competition for these people can be significant. If we are unable to hire and/or retain qualified employees and/or if we do not effectively invest in systems and processes to manage and support our rapid growth and the challenges and difficulties associated with managing a larger, more complex business, and/or if we cannot effectively manage and integrate our increasingly diverse and global platform, there could be a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

NEW MYLAN EXPECTS TO BE TREATED AS A NON-U.S. CORPORATION FOR U.S. FEDERAL INCOME TAX PURPOSES. ANY CHANGES TO THE TAX LAWS OR CHANGES IN OTHER LAWS, REGULATIONS, RULES, OR INTERPRETATIONS THEREOF APPLICABLE TO INVERTED COMPANIES AND THEIR AFFILIATES, WHETHER ENACTED BEFORE OR AFTER THE TRANSACTION, MAY MATERIALLY ADVERSELY AFFECT NEW MYLAN.

Under current U.S. law, we believe that we should not be treated as a U.S. corporation for U.S. federal income tax purposes as a result of the Transaction. Changes to Section 7874 of the Internal Revenue Code of 1986, as amended (the “Code”) or the U.S. Treasury Regulations promulgated thereunder, or interpretations thereof, could affect our status as a non-U.S. corporation for U.S. federal income tax purposes. Any such changes could have prospective or retroactive application, and may apply even if enacted or promulgated now that the Transaction has closed. If we were to be treated as a U.S. corporation for U.S. federal income tax purposes, we would likely be subject to significantly greater U.S. tax liability than currently contemplated as a non-U.S. corporation.

On August 5, 2014, the U.S. Treasury Department announced that it is reviewing a broad range of authorities for possible administrative actions that could limit the ability of a U.S. corporation to complete a transaction in which it becomes a subsidiary of a non-U.S. corporation (commonly known as an “inversion transaction”) or reduce certain tax benefits after an inversion transaction takes place. On September 22, 2014, the U.S. Treasury Department issued a notice announcing its intention to promulgate certain regulations that will apply to inversion transactions completed on or after September 22, 2014.

In the notice, the U.S. Treasury Department also announced that it expects to issue additional guidance to further limit certain inversion transactions. In particular, it is considering regulations that may limit income tax treaty eligibility and the ability of certain foreign-owned U.S. corporations to deduct certain interest payments (so-called “earnings stripping”). Any such future guidance will apply prospectively, but to the extent it applies only to companies that have completed inversion transactions, it will specifically apply to companies that have completed such transactions on or after September 22, 2014. Additionally, there have been recent legislative proposals intended to limit or discourage

inversion transactions. Any such future regulatory or legislative actions regarding inversion transactions, if taken, could apply to us, could disadvantage us as compared to other corporations, including non-U.S. corporations that have completed inversion transactions prior to

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September 22, 2014, and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

IF THE INTERCOMPANY TERMS OF CROSS BORDER ARRANGEMENTS THAT WE HAVE AMONG OUR SUBSIDIARIES ARE DETERMINED TO BE INAPPROPRIATE OR INEFFECTIVE, OUR TAX LIABILITY MAY INCREASE.

We have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations which include exposures on intercompany terms of cross-border arrangements among our subsidiaries (including intercompany loans, sales, and services agreements) in relation to various aspects of our business, including manufacturing, marketing, sales, and delivery functions. Although we believe our cross border arrangements between affiliates are based upon internationally accepted standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in their country, which may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

UNANTICIPATED CHANGES IN OUR TAX PROVISIONS OR EXPOSURE TO ADDITIONAL INCOME TAX LIABILITIES AND CHANGES IN INCOME TAX LAWS AND TAX RULINGS MAY HAVE A SIGNIFICANT ADVERSE IMPACT ON OUR EFFECTIVE TAX RATE AND INCOME TAX EXPENSE.

We are subject to income taxes in many jurisdictions. Significant analysis and judgment are required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our income tax provisions and accruals.

Additionally, changes in the effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by taxing authorities, and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

Finally, potential changes to income tax laws in the U.S. include measures which would defer the deduction of interest expense related to deferred income; determine the foreign tax credit on a pooling basis; tax currently excess returns associated with transfers of intangibles offshore; and limit earnings stripping by expatriated entities. In addition, proposals have been made to encourage manufacturing in the U.S., including reduced rates of tax and increased deductions related to manufacturing. We cannot determine whether these proposals will be modified or enacted, whether other proposals unknown at this time will be made, or the extent to which the corporate tax rate might be reduced and lessen the adverse impact of some of these proposals. If enacted, and depending on its precise terms, such legislation could materially increase our overall effective income tax rate and income tax expense and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

OUR BUSINESS RELATIONSHIPS, INCLUDING CUSTOMER RELATIONSHIPS, MAY BE SUBJECT TO DISRUPTION DUE TO THE TRANSACTION.

Parties with which we currently do business or may do business in the future, including customers and suppliers, may experience uncertainty associated with the Transaction, including with respect to current or future business relationships with us. As a result, our business relationships may be subject to disruptions if customers, suppliers, and others attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than us. For example, certain customers and collaborators have contractual consent rights or termination rights that may have been triggered by a change of control or assignment of the rights and obligations of contracts that were transferred in the Transaction. In addition, our contract manufacturing business could be impaired if existing or potential customers determine not to continue or initiate contract manufacturing relationships with us. These disruptions could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

IF COUNTERPARTIES TO CERTAIN AGREEMENTS WITH US DID NOT CONSENT TO THE TRANSACTION, CHANGE-OF-CONTROL RIGHTS UNDER THOSE AGREEMENTS MAY HAVE BEEN TRIGGERED AS A RESULT OF THE TRANSACTION, WHICH COULD CAUSE US TO LOSE THE BENEFIT OF SUCH AGREEMENTS AND INCUR MATERIAL LIABILITIES OR REPLACEMENT COSTS.

We are parties to agreements (including certain agreements with AbbVie Inc.) that contain change-of-control, anti-assignment, or certain other provisions that were triggered as a result of the Transaction. If the counterparties to these agreements did not consent to the Transaction, the counterparties may have the ability to exercise certain rights (including termination rights), resulting in us incurring liabilities as a consequence of breaching such agreements, or causing us to lose the benefit of such agreements or incur costs in seeking replacement agreements.

FOR A CERTAIN PERIOD AFTER CONSUMMATION OF THE TRANSACTION, WE MAY NOT BE PERMITTED TO ENTER INTO CERTAIN TRANSACTIONS THAT MIGHT OTHERWISE BE BENEFICIAL TO OUR SHAREHOLDERS.

For at least 90 days after closing of the Transaction, we may not, without the consent of Abbott, issue, or agree to issue, any securities or equity rights, other than issuances of our ordinary shares in connection with the exercise of outstanding equity rights. The foregoing prohibitions could have the effect of delaying other strategic transactions and may, in some cases, make it impossible to pursue other strategic transactions that are available only for a limited time. MYLAN SHAREHOLDERS PRIOR TO THE TRANSACTION NOW OWN A SMALLER SHARE OF NEW MYLAN FOLLOWING THE CONSUMMATION OF THE TRANSACTION.

Following the consummation of the Transaction, Mylan shareholders owned the same number of shares of New Mylan that they owned in Mylan immediately before closing (and no longer hold any shares in Mylan). Each New Mylan ordinary share, however, represented a smaller ownership percentage of a significantly larger company. As a result of the Transaction, Mylan shareholders owned approximately 78% of the outstanding voting securities of New Mylan and Abbott's subsidiaries owned approximately 22% of the outstanding voting securities of New Mylan.

SALES OR HEDGING ARRANGEMENTS INVOLVING NEW MYLAN ORDINARY SHARES AFTER THE TRANSACTION MAY NEGATIVELY AFFECT THE MARKET PRICE OF NEW MYLAN ORDINARY SHARES.

The New Mylan ordinary shares issued to Abbott's subsidiaries in the Transaction are generally eligible for immediate resale. Abbott and its subsidiaries are also permitted to enter into certain hedging arrangements with respect to those New Mylan ordinary shares. The market price of New Mylan ordinary shares could decline as a result of sales or hedging arrangements involving a large number of New Mylan ordinary shares after the consummation of the Transaction or the perception that these sales or hedging arrangements could occur. These sales or hedging arrangements, or the possibility that these sales or hedging arrangements may occur, also might make it more difficult for New Mylan to obtain additional capital by selling equity securities in the future at a time and at a price that New Mylan deems appropriate.

THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED AND WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE REGULATIONS.

The pharmaceutical industry is subject to regulation by various governmental authorities. For instance, we must comply with requirements of the FDA and requirements from regulatory agencies in our other markets with respect to the research, development, manufacture, quality, safety, labeling, sale, distribution, marketing, advertising, and promotion of pharmaceutical products. Failure to comply with regulations of the FDA and other regulators could result in a range of fines, penalties, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, suspension of the applicable regulator's review of our submissions, enforcement actions, injunctions, and/or criminal prosecution. Under certain circumstances, the regulators may also have the authority to revoke previously granted drug approvals.

In addition to the drug approval process, government agencies also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and other similar regulators in other countries. Products manufactured in our facilities must be made in a manner consistent with current good manufacturing practices or similar standards in each territory in which we manufacture. Compliance with such regulations requires substantial expenditures of time, money, and effort in such areas as production and quality control to ensure compliance. The FDA and other agencies periodically inspect our manufacturing facilities for compliance. Regulatory approval to manufacture a drug is site-specific. Failure to comply with good manufacturing practices and other regulatory standards at one of our or our partners' or suppliers' manufacturing facilities could result in an adverse action brought by the FDA or other regulatory bodies, which could include fines, penalties, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, suspension of the applicable regulator's review of our submissions, enforcement actions, injunctions, and/or criminal prosecution or other adverse actions.

If any regulatory body were to delay, withhold, or withdraw approval of an application, or require a recall or other adverse product action, or require one of our manufacturing facilities to cease or limit production, our business could be adversely affected. Delay and cost in obtaining FDA or other regulatory approval to manufacture at a different facility also could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

Although we have internal regulatory compliance programs and policies, there is no guarantee that these programs and policies, as currently designed, will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations. Additionally, despite our efforts at compliance, from time to time we receive notices of manufacturing and quality-related observations following inspections by regulatory authorities around the world, as well as official agency correspondence regarding compliance. We may receive similar observations and correspondence in the future. If we were deemed to be deficient in any significant way, or if any of the noted risks occur, our business, financial condition, results of operations, cash flows, and/or share price could be materially affected.

We are subject to various federal, state and local laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment and those related to climate change. If changes to such environmental laws and regulations are made in the future that require significant changes in our operations, or if we engage in the development and manufacturing of new products requiring new or different environmental or other controls, or if we are found to have violated any applicable rules, we may be required to expend significant funds. Such changes, delays, and/or suspensions of activities or the occurrence of any of the above risks, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THE USE OF LEGAL, REGULATORY, AND LEGISLATIVE STRATEGIES BY BOTH BRAND AND GENERIC COMPETITORS, INCLUDING BUT NOT LIMITED TO "AUTHORIZED GENERICS" AND REGULATORY PETITIONS, AS WELL AS THE POTENTIAL IMPACT OF PROPOSED AND NEW LEGISLATION, MAY INCREASE COSTS ASSOCIATED WITH THE INTRODUCTION OR MARKETING OF OUR GENERIC PRODUCTS, COULD DELAY OR PREVENT SUCH INTRODUCTION, AND COULD SIGNIFICANTLY REDUCE OUR PROFIT.

Our competitors, both branded and generic, often pursue strategies to prevent, delay, or eliminate competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time or after generic competition initially enters the market;
- launching a generic version of their own branded product prior to or at the same time or after generic competition initially enters the market;
- filing petitions with the FDA or other regulatory bodies seeking to prevent or delay approvals, including timing the filings so as to thwart generic competition by causing delays of our product approvals;
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seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or to meet other requirements for approval, and/or to prevent regulatory agency review of applications, such as through the establishment of patent linkage (laws barring the issuance of regulatory approvals prior to patent expiration);
• initiating legislative or other efforts to limit the substitution of generic versions of brand pharmaceuticals;

- filing suits for patent infringement and other claims that may delay or prevent regulatory approval, manufacture, and/or scale of generic products;
- introducing “next-generation” products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the generic or the reference product for which we seek regulatory approval;
- persuading regulatory bodies to withdraw the approval of brand name drugs for which the patents are about to expire and converting the market to another product of the brand company on which longer patent protection exists;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other methods; and
- seeking to obtain new patents on drugs for which patent protection is about to expire.

In the U.S., some companies have lobbied Congress for amendments to the Hatch-Waxman Act that would give them additional advantages over generic competitors. For example, although the term of a company’s drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials rather than the one-half year that is currently permitted.

If proposals like these in the U.S., Europe, or in other countries where we or our partners and suppliers operate were to become effective, or if any other actions by our competitors and other third parties to prevent or delay activities necessary to the approval, manufacture, or distribution of our products are successful, our entry into the market and our ability to generate revenues associated with new products may be delayed, reduced, or eliminated, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

IF WE ARE UNABLE TO SUCCESSFULLY INTRODUCE NEW PRODUCTS IN A TIMELY MANNER, OUR FUTURE REVENUE MAY BE ADVERSELY AFFECTED.

Our future revenues and profitability will depend, in part, upon our ability to successfully develop, license, or otherwise acquire and commercialize new generic and patent or statutorily protected pharmaceutical products in a timely manner. Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and the market is not yet proven as well as for complex generic drugs and biosimilars. Likewise, product licensing involves inherent risks, including among others uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to whether the supply of product meets certain specifications or terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new and complex drugs, also requires substantial time, effort and financial resources. We, or a partner, may not be successful in commercializing any of such products on a timely basis, if at all, which could adversely affect our business, financial condition, results of operations, cash flows, and/or share price.

Before any prescription drug product, including generic drug products, can be marketed, marketing authorization approval is required by the relevant regulatory authorities and/or national regulatory agencies (for example the FDA in the U.S. and the EMA in the EU). The process of obtaining regulatory approval to manufacture and market new and generic pharmaceutical products is rigorous, time consuming, costly, and unpredictable. Outside the U.S., the approval process may be more or less rigorous, depending on the country, and the time required for approval may be longer or shorter than that required in the U.S. Bioequivalence studies conducted in one country may not be accepted in other countries, the requirements for approval may differ among countries, and the approval of a pharmaceutical product in one country does not necessarily mean that the product will be approved in another country. We, or a partner or supplier, may be unable to obtain requisite approvals on a timely basis, or at all, for new generic or branded products that we may develop, license or otherwise acquire. Moreover, if we obtain regulatory approval for a drug, it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which could in turn restrict our potential market for the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalence testing, as well as in anticipation of the product’s launch. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of this inventory becoming obsolete.

The approval process for generic pharmaceutical products often results in the relevant regulatory agency granting final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces us to face immediate competition when we introduce a generic product into

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the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price, margin, and sales erosion over the generic product life cycle.

In the U.S., the Hatch-Waxman Act provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with timely Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, the applicant generally enjoys higher market share, net revenues, and gross margin for that generic product. However, our ability to obtain 180 days of generic marketing exclusivity may be dependent upon our ability to obtain FDA approval or tentative approval within an applicable time period of the FDA's acceptance of our ANDA. If we are unable to obtain approval or tentative approval within that time period, we may risk forfeiture of such marketing exclusivity. Even if we obtain FDA approval for our generic drug products, if we are not the first ANDA applicant to challenge a listed patent for such a product, we may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications.

In Europe and other countries and regions, there is no exclusivity period for the first generic product. The EMA or national regulatory agencies may grant marketing authorizations to any number of generics.

In addition, in other jurisdictions outside the U.S., we may face similar regulatory requirements and constraints. If we are unable to navigate our products through all of the regulatory requirements we face in a timely manner, or upon the occurrence of any of the other above risks, there could be an adverse effect on our product introduction plans, business, financial condition, results of operations, cash flows, and/or share price.

WE EXPEND A SIGNIFICANT AMOUNT OF RESOURCES ON RESEARCH AND DEVELOPMENT EFFORTS THAT MAY NOT LEAD TO SUCCESSFUL PRODUCT INTRODUCTIONS.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology, including our generic biologics program and respiratory platform. We conduct R&D primarily to enable us to manufacture and market approved pharmaceuticals in accordance with applicable regulations. We also partner with third parties to develop products. Typically, research expenses related to the development of innovative or complex compounds and the filing of marketing authorization applications for innovative and complex compounds (such as NDAs and biosimilar applications in the U.S.) are significantly greater than those expenses associated with the development of and filing of marketing authorization applications for most generic products (such as ANDAs in the U.S. and abridged applications in Europe). As we and our partners continue to develop new and/or complex products, our research expenses will likely increase. Because of the inherent risk associated with R&D efforts in our industry, including the high cost and uncertainty of conducting clinical trials (where required) particularly with respect to new and/or complex drugs, our, or a partner's, research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the relevant regulatory bodies. Also, after we submit a marketing authorization application for a new compound or generic product, the relevant regulatory authority may change standards and/or request that we conduct additional studies or evaluations and, as a result, we may incur approval delays as well as total R&D costs to develop a particular product in excess of what we anticipated. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on R&D efforts and are not able, ultimately, to introduce successful new and/or complex products as a result of those efforts, there could be a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

EVEN AFTER OUR PRODUCTS RECEIVE REGULATORY APPROVAL, SUCH PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE.

Even if we are able to obtain regulatory approvals for our pharmaceutical products, generic or branded, the success of those products is dependent upon market acceptance. Levels of market acceptance for our products could be impacted by several factors, including but not limited to:

- the availability of alternative products from our competitors;
- the price of our products relative to that of our competitors;
- the timing of our market entry;
- the ability to market our products effectively to the different levels in the distribution chain;
- other competitor actions; and
- the continued acceptance of and/or reimbursement for our products by government and private formularies and/or third party payors.

Additionally, studies of the proper utilization, safety, and efficacy of pharmaceutical products are being conducted by the industry, government agencies, and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of previously marketed as well as future products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs, such as the need for a patient registry, as well as delays in approvals. The occurrence of any of the above risks could adversely affect our profitability, business, financial condition, results of operations, cash flows, and/or share price.

THE DEVELOPMENT, MANUFACTURE AND SALE OF BIOSIMILAR PRODUCTS POSES UNIQUE RISKS, AND OUR FAILURE TO SUCCESSFULLY INTRODUCE BIOSIMILAR PRODUCTS COULD HAVE A NEGATIVE IMPACT ON OUR BUSINESS AND FUTURE OPERATING RESULTS.

We and our partners and suppliers are actively working to develop and commercialize biosimilar products - that is, a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of safety, purity and potency. However, significant uncertainty remains concerning both the regulatory pathway in the U.S. and in other countries to obtain regulatory approval of biosimilar products, and the commercial pathway to successfully market and sell such products. In particular, although recently enacted legislation authorizes the FDA to create a regulatory pathway for the review and approval of such products, significant uncertainty remains concerning the establishment of this regulatory regime, as well as the commercial steps necessary to successfully market and sell such products. The costs of development and approval, along with the likelihood of success for our biosimilar candidates, however, will be dependent upon any final regulations issued by the FDA or other relevant regulatory authorities.

Moreover, biosimilar products will likely be subject to extensive patent clearances and patent infringement litigation, which could delay or prevent the commercial launch of a product for many years. If we are unable to obtain FDA or other non-U.S. regulatory authority approval for our products, as needed, such products may not be commercially successful and may not generate profits in amounts that are sufficient to offset the amount invested to obtain such approvals. Market success of biosimilar products will depend on demonstrating to regulators, patients, physicians and payors (such as insurance companies) that such products are safe and efficacious compared to other existing products yet offer a more competitive price or other benefit over existing therapies. In addition, the development and manufacture of biosimilars pose unique risks related to the supply of the materials needed to manufacture biosimilars. Access to and the supply of necessary biological materials may be limited, and government regulations restrict access to and regulate the transport and use of such materials. Depending on the outcome of the foregoing risks, we may not be able to generate future sales of biosimilar products in certain jurisdictions and may not realize the anticipated benefits of our investments in the development, manufacture and sale of such products. If our development efforts do not result in the development and timely approval of biosimilar products or if such products, once developed and approved, are not commercially successful, or upon the occurrence of any of the above risks, our business, financial condition, results of operations, cash flows, and/or share price could be materially adversely affected.

OUR BUSINESS IS HIGHLY DEPENDENT UPON MARKET PERCEPTIONS OF US, OUR BRANDS, AND THE SAFETY AND QUALITY OF OUR PRODUCTS, AND MAY BE ADVERSELY IMPACTED BY NEGATIVE PUBLICITY OR FINDINGS.

Market perceptions of us are very important to our business, especially market perceptions of our company and brands and the safety and quality of our products. If we, our partners and suppliers, or our brands suffer from negative publicity, or if any of our products or similar products which other companies distribute are subject to market withdrawal or recall or are proven to be, or are claimed to be, ineffective or harmful to consumers, then this could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price. Also, because we are dependent on market perceptions, negative publicity associated with product quality, patient illness, or other adverse effects resulting from, or perceived to be resulting from, our products, or our partners' and suppliers' manufacturing facilities, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THE ILLEGAL DISTRIBUTION AND SALE BY THIRD PARTIES OF COUNTERFEIT VERSIONS OF OUR PRODUCTS OR OF STOLEN PRODUCTS COULD HAVE A NEGATIVE IMPACT ON OUR REPUTATION AND OUR BUSINESS.

The pharmaceutical drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products that do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of API, or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants, or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation, and our business.

Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price. **OUR COMPETITORS, INCLUDING BRANDED PHARMACEUTICAL COMPANIES, AND/OR OTHER THIRD PARTIES, MAY ALLEGE THAT WE AND/OR OUR SUPPLIERS ARE INFRINGING UPON THEIR INTELLECTUAL PROPERTY, INCLUDING IN AN "AT RISK LAUNCH" SITUATION, IMPACTING OUR ABILITY TO LAUNCH A PRODUCT, AND/OR OUR ABILITY TO CONTINUE MARKETING A PRODUCT, AND/OR FORCING US TO EXPEND SUBSTANTIAL RESOURCES IN RESULTING LITIGATION, THE OUTCOME OF WHICH IS UNCERTAIN.**

Companies that produce branded pharmaceutical products and other patent holders routinely bring litigation against entities selling or seeking regulatory approval to manufacture and market generic forms of their branded products, as well as other entities involved in the manufacture, supply, testing, marketing, and other aspects relating to active pharmaceutical ingredients and finished pharmaceutical products. These companies and other patent holders allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant for a generic product license as well as others who may be involved in some aspect of the research, production, distribution, or testing process. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic products. If patents are held valid and infringed by our products in a particular jurisdiction, we and/or our supplier(s) or partner(s) would, unless we or the supplier(s) or partner(s) could obtain a license from the patent holder, need to cease manufacturing and other activities, including but not limited to selling in that jurisdiction, and may need to surrender or withdraw the product, or destroy existing stock in that jurisdiction.

There also may be situations where we use our business judgment and decide to manufacture, market, and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an "at-risk launch"). The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent holder and not necessarily by the profits earned by the infringer. In the case of a finding by a court of willful infringement, the definition of which is subjective, such damages may be increased by an

additional 200%. Moreover, because of the discount pricing typically involved with bioequivalent (generic) products, patented branded products generally realize a

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substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation, or a judicial order preventing us or our suppliers and partners from manufacturing, marketing, selling, and/or other activities necessary to the manufacture and distribution of our products, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price. For information regarding legal proceedings, refer to Note 14, "Contingencies," in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

IF WE OR ANY PARTNER OR SUPPLIER FAIL TO OBTAIN OR ADEQUATELY PROTECT OR ENFORCE OUR INTELLECTUAL PROPERTY RIGHTS, THEN WE COULD LOSE REVENUE UNDER OUR LICENSING AGREEMENTS OR LOSE SALES TO GENERIC COPIES OF OUR BRANDED PRODUCTS.

Our success, particularly in our specialty business, depends in part on our or any partner's or supplier's ability to obtain, maintain and enforce patents, and protect trade secrets, know-how, and other proprietary information. Our ability to commercialize any branded product successfully will largely depend upon our or any partner's or supplier's ability to obtain and maintain patents of sufficient scope to lawfully prevent third-parties from developing infringing products. In the absence of patent and trade secret protection, competitors may adversely affect our branded products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering the composition of, methods of making, and/or methods of using, our branded products and branded product candidates. We may not be issued patents based on patent applications already filed or that we file in the future. Further, due to other factors that affect patentability, and if patents are issued, they may be insufficient in scope to cover or otherwise protect our branded products. Patents are national in scope and therefore the issuance of a patent in one country does not ensure the issuance of a patent in any other country.

Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of significant litigation. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the U.S. Patent and Trademark Office or any other governmental agency may commence opposition or interference proceedings involving, or consider other challenges to, our patents or patent applications.

Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, and could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

BOTH OUR GENERICS AND SPECIALTY BUSINESSES DEVELOP, FORMULATE, MANUFACTURE, OR IN-LICENSE AND MARKET PRODUCTS THAT ARE SUBJECT TO ECONOMIC RISKS RELATING TO INTELLECTUAL PROPERTY RIGHTS, COMPETITION, AND MARKET UNPREDICTABILITY.

Our products may be subject to the following risks, among others:

- limited patent life, or the loss of patent protection;
- competition from generic or other branded products;
- reductions in reimbursement rates by government and other third-party payors;
- importation by consumers;
- product liability;
- drug research and development risks; and
- unpredictability with regard to establishing a market.

In addition, developing and commercializing branded products is generally more costly than generic products. If such business expenditures do not ultimately result in the launch of commercially successful brand products, or if any of the risks above were to occur, there could be a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE FACE VIGOROUS COMPETITION FROM OTHER PHARMACEUTICAL MANUFACTURERS THAT THREATENS THE COMMERCIAL ACCEPTANCE AND PRICING OF OUR PRODUCTS.

The pharmaceutical industry is highly competitive. We face competition from many U.S. and non-U.S. manufacturers, some of whom are significantly larger than we are. Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including but not limited to the possibility that they may have:

- proprietary processes or delivery systems;
- larger or more productive research and development and marketing staffs;
- larger or more efficient production capabilities in a particular therapeutic area;
- more experience in preclinical testing and human clinical trials;
- more products; or
- more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

The occurrence of any of the above risks could have an adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR REVENUES, GROSS PROFIT, OR NET EARNINGS FROM TIME TO TIME.

Sales of a limited number of our products from time to time represent a significant portion of our revenues, gross profit, and net earnings. For the years ended December 31, 2014 and 2013, our top ten products in terms of sales, in the aggregate, represented approximately 33% and 31%, respectively, of our consolidated total revenues. If the volume or pricing of our largest selling products declines in the future, our business, financial condition, results of operations, cash flows, and/or share price could be materially adversely affected.

OUR BUSINESS COULD BE NEGATIVELY AFFECTED BY THE PERFORMANCE OF OUR COLLABORATION PARTNERS AND SUPPLIERS.

We have entered into strategic alliances with partners and suppliers to develop, manufacture, market and/or distribute certain products, and/or certain components of our products, in various markets. We commit substantial effort, funds and other resources to these various collaborations. There is a risk that the investments made by us in these collaborative arrangements will not generate financial returns. While we believe our relationships with our partners and suppliers generally are successful, disputes or conflicting priorities and regulatory or legal intervention could be a source of delay or uncertainty as to the expected benefits of the collaboration. A failure or inability of our partners or suppliers to fulfill their collaboration obligations, or the occurrence of any of the risks above, could have an adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

A SIGNIFICANT PORTION OF OUR REVENUES IS DERIVED FROM SALES TO A LIMITED NUMBER OF CUSTOMERS.

A significant portion of our revenues is derived from sales to a limited number of customers. If we were to experience a significant reduction in or loss of business with one or more such customers, or if one or more such customers were to experience difficulty in paying us on a timely basis, our business, financial condition, results of operations, cash flows, and/or share price could be materially adversely affected.

During the years ended December 31, 2014, 2013 and 2012, sales to Cardinal Health, Inc. were approximately 12%, 15% and 14%, respectively; sales to McKesson Corporation were approximately 19%, 14% and 13%, respectively; sales to AmeriSourceBergen Corporation were approximately 13%, 10% and 7%, respectively of consolidated net sales.

WE MAY EXPERIENCE DECLINES IN THE SALES VOLUME AND PRICES OF OUR PRODUCTS AS THE RESULT OF THE CONTINUING TREND TOWARD CONSOLIDATION OF CERTAIN CUSTOMER GROUPS, SUCH AS THE WHOLESALE DRUG DISTRIBUTION AND RETAIL PHARMACY INDUSTRIES, AS WELL AS THE EMERGENCE OF LARGE BUYING GROUPS.

A significant amount of our sales are to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of generic pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to attempt to extract price discounts on our products. The occurrence of any of the above risks could adversely affect our business, financial condition, results of operations, cash flows, and/or share price.

WE DEPEND TO A LARGE EXTENT ON THIRD-PARTY SUPPLIERS AND DISTRIBUTORS FOR RAW MATERIALS, PARTICULARLY THE CHEMICAL COMPOUND(S) THAT CONSTITUTE THE ACTIVE PHARMACEUTICAL INGREDIENTS THAT WE USE TO MANUFACTURE OUR PRODUCTS, AS WELL AS CERTAIN FINISHED GOODS, INCLUDING CERTAIN CONTROLLED SUBSTANCES. THESE THIRD-PARTY SUPPLIERS AND DISTRIBUTORS MAY EXPERIENCE DELAYS IN OR INABILITY TO SUPPLY US WITH RAW MATERIALS NECESSARY TO THE DEVELOPMENT AND/OR MANUFACTURE OF OUR PRODUCTS.

We purchase certain API (i.e., the chemical compounds that produce the desired therapeutic effect in our products) and other materials and supplies that we use in our manufacturing operations, as well as certain finished products, from many different foreign and domestic suppliers.

In certain cases, we have listed only one supplier in our applications with regulatory agencies, and there is no guarantee that we will always have timely and sufficient access to a critical raw material or finished product supplied by third parties, even when we have more than one supplier. An interruption in the supply of a single-sourced or any other raw material, including the relevant API, or in the supply of finished product, could cause our business, financial condition, results of operations, cash flows, and/or share price to be materially adversely affected. In addition, our manufacturing and supply capabilities could be adversely impacted by quality deficiencies in the products which our suppliers provide, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

We utilize controlled substances in certain of our current products and products in development, and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the DEA in the U.S., as well as similar laws in other countries where we operate. These laws relate to the manufacture, shipment, storage, sale, and use of controlled substances. The DEA and other regulatory agencies limit the availability of the active ingredients used in certain of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA and other regulatory agencies for procurement quota in order to obtain these substances. Any delay or refusal by the DEA or such regulatory agencies in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THE SUPPLY OF API INTO EUROPE MAY BE NEGATIVELY AFFECTED BY RECENT REGULATIONS PROMULGATED BY THE EUROPEAN UNION.

Since July 2, 2013, all API imported into the EU has needed to be certified as complying with the good manufacturing practice (“GMP”) standards established by the EU, as stipulated by the International Conference for Harmonization. These new regulations place the certification requirement on the regulatory bodies of the exporting countries.

Accordingly, the national regulatory authorities of each exporting country must: (i) ensure that all manufacturing plants within their borders that export API into the EU comply with EU manufacturing standards and (ii) for each API exported, present a written document confirming that the exporting plant conforms to EU manufacturing standards.

The imposition of this responsibility on the governments of the nations exporting an API may cause delays in delivery or shortages of an API necessary to manufacture our products, as certain governments may not be willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API may prevent us from manufacturing, or cause us to have to cease manufacture of, certain products, or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers unable to export. The occurrence of any of

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the above risks could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE HAVE A LIMITED NUMBER OF MANUFACTURING FACILITIES AND CERTAIN THIRD PARTY SUPPLIERS PRODUCING A SUBSTANTIAL PORTION OF OUR PRODUCTS.

A substantial portion of our capacity, as well as our current production, is attributable to a limited number of manufacturing facilities and certain third party suppliers. A significant disruption at any one of such facilities within our internal or third party supply chain, even on a short-term basis, whether due to a labor strike, failure to reach acceptable agreement with labor and unions, adverse quality or compliance observation, infringement of intellectual property rights, act of God, civil or political unrest, export or import restrictions, or other events could impair our ability to produce and ship products to the market on a timely basis and could, among other consequences, subject us to exposure to claims from customers. Any of these events could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

The PPACA of 2010 includes a provision requiring the CMS to publish a weighted average Average Manufacturer Price ("AMP") for all multi-source drugs. The provision was effective October 1, 2010; however, weighted average AMP's have not yet been published by CMS, except in draft form, and have not been implemented for use in the calculation of Federal Upper Limits. Although the weighted average AMP would not reveal Mylan's individual AMP, publishing a weighted average AMP available to customers and the public at large could negatively affect our leverage in commercial price negotiations.

In addition, as also disclosed herein, a number of state and federal government agencies are conducting investigations of manufacturers' reporting practices with respect to Average Wholesale Prices ("AWP"). The government has alleged that reporting of inflated AWP has led to excessive payments for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid.

Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any failure to comply with the above laws and regulations, and any such penalties or sanctions could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE MAY EXPERIENCE REDUCTIONS IN THE LEVELS OF REIMBURSEMENT FOR PHARMACEUTICAL PRODUCTS BY GOVERNMENTAL AUTHORITIES, HMOS, OR OTHER THIRD-PARTY PAYORS. IN ADDITION, THE USE OF TENDER SYSTEMS AND OTHER FORMS OF PRICE CONTROL COULD REDUCE PRICES FOR OUR PRODUCTS OR REDUCE OUR MARKET OPPORTUNITIES.

Various governmental authorities (including, among others, the U.K. National Health Service and the German statutory health insurance scheme) and private health insurers and other organizations, such as HMOs in the U.S., provide

reimbursements or subsidies to consumers for the cost of certain pharmaceutical products. Demand for our products depends in part on the extent to which such reimbursement is available. In the U.S., third-party payors increasingly challenge the pricing of pharmaceutical products. This trend and other trends toward the growth of HMOs, managed health care, and legislative health care reform create significant uncertainties regarding the future levels of reimbursement for pharmaceutical products. Further, any reimbursement may be reduced in the future to the point that market demand for our products and/or our profitability declines. Such a decline could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

In addition, a number of markets in which we operate have implemented or may implement tender systems or other forms of price controls for generic pharmaceuticals in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender.

Certain other countries may consider the implementation of a tender system or other forms of price controls. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions. Failing to win tenders, or the implementation of similar systems or other forms of price controls in other markets leading to further price declines, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

LEGISLATIVE OR REGULATORY PROGRAMS THAT MAY INFLUENCE PRICES OF PHARMACEUTICAL PRODUCTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

Current or future federal, state or foreign laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for our products. For example, programs in existence in certain states in the U.S. seek to broadly set prices, within those states, through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular state Medicare and/or Medicaid programs, or changes required in the way in which Medicare and/or Medicaid rebates are calculated under such programs, could adversely affect the prices we receive for our products and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

In order to control expenditure on pharmaceuticals, most member states in the EU regulate the pricing of products and, in some cases, limit the range of different forms of pharmaceuticals available for prescription by national health services. These controls can result in considerable price differences between member states.

Several countries in which we operate have implemented, or plan to or may implement, government mandated price reductions and/or other controls. When such price cuts occur, pharmaceutical companies have generally experienced significant declines in revenues and profitability and uncertainties continue to exist within the market after the price decrease. Such price reductions or controls could have an adverse effect on our business, and as uncertainties are resolved or if other countries in which we operate enact similar measures, they could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

HEALTH CARE REFORM LEGISLATION COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for, health care services in the U.S., and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. The PPACA and The Health Care and Education and Reconciliation Act of 2010 (H.R. 4872), which amends the PPACA (collectively, the "Health Reform Laws"), were signed into law in March 2010. While the Health Reform Laws may increase the number of patients who have insurance coverage for our products, they also include provisions such as the assessment of a pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay

for coverage of their drugs by Medicaid programs.

We are unable to predict the future course of federal or state health care legislation. The Health Reform Laws and further changes in the law or regulatory framework that reduce our revenues or increase our costs could have a material adverse effect on our business, financial condition, results of operations and/or cash flow, and could cause the market value of our common stock to decline.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices,

patient eligibility and/or reimbursement levels to control costs for the government-sponsored health care system. These systems of price regulations may lead to inconsistent and lower prices. Within the EU and in other countries, the availability of our products in some markets at lower prices undermines our sales in other markets with higher prices. Additionally, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may also impair our ability to obtain acceptable prices in existing and potential new markets, and may create the opportunity for third party cross border trade.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE ARE INVOLVED IN VARIOUS LEGAL PROCEEDINGS AND CERTAIN GOVERNMENT INQUIRIES AND MAY EXPERIENCE UNFAVORABLE OUTCOMES OF SUCH PROCEEDINGS OR INQUIRIES.

We are or may be involved in various legal proceedings and certain government inquiries or investigations, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract, and claims involving Medicare and/or Medicaid reimbursements, or laws relating to sales and marketing practices, some of which are described in our periodic reports, that involve claims for, or the possibility of, fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties and exclusion from participation in various government health-care-related programs. With respect to government antitrust enforcement and private plaintiff litigation of so-called “pay for delay” patent settlements, large verdicts, settlements or government fines are possible, especially in the U.S. and E.U. If any of these legal proceedings or inquiries were to result in an adverse outcome, the impact could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

With respect to product liability, we maintain a combination of self-insurance (including through our wholly owned captive insurance subsidiary) and commercial insurance to protect against and manage a portion of the risks involved in conducting our business. Although we carry insurance, we believe that no reasonable amount of insurance can fully protect against all such risks because of the potential liability inherent in the business of producing pharmaceuticals for human consumption. Emerging developments in the U.S. legal landscape relative to the liability of generic pharmaceutical manufacturers for certain product liabilities claims could increase our exposure litigation costs and damages. To the extent that a loss occurs, depending on the nature of the loss and the level of insurance coverage maintained, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

In addition, in limited circumstances, entities that we acquired are party to litigation in matters under which we are, or may be, entitled to indemnification by the previous owners. Even in the case of indemnification, there are risks inherent in such indemnities and, accordingly, there can be no assurance that we will receive the full benefits of such indemnification, or that we will not experience an adverse result in a matter that is not indemnified, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE ARE SUBJECT TO THE U.S. FOREIGN CORRUPT PRACTICES ACT AND SIMILAR WORLDWIDE ANTI-CORRUPTION LAWS, WHICH IMPOSE RESTRICTIONS ON CERTAIN CONDUCT AND MAY CARRY SUBSTANTIAL FINES AND PENALTIES.

We are subject to the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws in other jurisdictions. These laws generally prohibit companies and their intermediaries from engaging in bribery or making other prohibited payments to government officials for the purpose of obtaining or retaining business, and some have record keeping requirements. The failure to comply with these laws could result in substantial criminal and/or monetary penalties. We operate in jurisdictions that have experienced corruption, bribery, pay-offs and other similar practices from time-to-time and, in certain circumstances, such practices may be local custom. We have implemented internal control policies and procedures that mandate compliance with these anti-corruption laws. However, we cannot be certain that

these policies and procedures will protect us against liability. There can be no assurance that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or agents are found to have engaged in such practices, we could suffer severe criminal or civil penalties and other consequences that could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

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OUR FAILURE TO COMPLY WITH APPLICABLE ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY LAWS AND REGULATIONS WORLDWIDE COULD ADVERSELY IMPACT OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR SHARE PRICE.

We are subject to various federal, state and local laws and regulations concerning, among other things, the environment, climate change, regulation of chemicals, employee safety and product safety. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of hazardous materials and pollutants into the environment. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could result in (i) our noncompliance with such environmental and occupational health and safety laws and regulations and (ii) regulatory enforcement actions or claims for personal injury and property damage against us. If an unapproved or illegal environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. The substantial unexpected costs we may incur could have a material and adverse effect on our business, financial condition, results of operations, cash flows, and/or share price. In addition, our environmental capital expenditures and costs for environmental compliance may increase substantially in the future as a result of changes in environmental laws and regulations, the development and manufacturing of a new product or increased development or manufacturing activities at any of our facilities. We may be required to expend significant funds and our manufacturing activities could be delayed or suspended, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE HAVE A NUMBER OF CLEAN ENERGY INVESTMENTS WHICH ARE SUBJECT TO VARIOUS RISKS AND UNCERTAINTIES.

We have invested in clean energy operations capable of producing refined coal that we believe qualify for tax credits under Section 45 of the Code. Our ability to claim tax credits under Section 45 of the Code depends upon the operations in which we have invested satisfying certain ongoing conditions set forth in Section 45 of the Code. These include, among others, the emissions reduction, “qualifying technology”, and “placed-in-service” requirements of Section 45 of the Code, as well as the requirement that at least one of the operations’ owners qualifies as a “producer” of refined coal. While we have received some degree of confirmation from the IRS relating to our ability to claim these tax credits, the IRS could ultimately determine that the operations have not satisfied, or have not continued to satisfy, the conditions set forth in Section 45 of the Code. Additionally, Congress could modify or repeal Section 45 of the Code and remove the tax credits retroactively.

In addition, Section 45 of the Code contains phase out provisions based upon the market price of coal, such that, if the price of coal rises to specified levels, we could lose some or all of the tax credits we expect to receive from these investments.

Finally, when the price of natural gas or oil declines relative to that of coal, some utilities may choose to burn natural gas or oil instead of coal. Market demand for coal may also decline as a result of an economic slowdown and a corresponding decline in the use of electricity. If utilities burn less coal, eliminate coal in the production of electricity or are otherwise unable to operate for an extended period of time, the availability of the tax credits would also be reduced. The occurrence of any of the above risks could adversely affect our business, financial condition, results of operations, cash flows, and/or share price.

THE SIGNIFICANT AND INCREASING AMOUNT OF INTANGIBLE ASSETS AND GOODWILL RECORDED ON OUR BALANCE SHEET, MAINLY RELATED TO ACQUISITIONS, MAY LEAD TO SIGNIFICANT IMPAIRMENT CHARGES IN THE FUTURE WHICH COULD LEAD US TO HAVE TO TAKE SIGNIFICANT CHARGES AGAINST EARNINGS.

We regularly review our long-lived assets, including identifiable intangible assets and goodwill, for impairment. Goodwill and indefinite-lived intangible assets are subject to impairment assessment at least annually. Other long-lived assets are reviewed when there is an indication that an impairment may have occurred. The amount of

goodwill and identifiable intangible assets on our consolidated balance sheet has increased significantly as a result of our acquisitions, and may increase further following future potential acquisitions. In addition, we may from time to time sell assets that we determine are not critical to our strategy or execution. Future events or decisions may lead to asset impairments and/or related charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could have a material adverse effect on our business, financial condition, results of operations, shareholder's equity, and/or share price.

WE MAY DECIDE TO SELL ASSETS, WHICH COULD ADVERSELY AFFECT OUR PROSPECTS AND OPPORTUNITIES FOR GROWTH.

We may from time to time consider selling certain assets if (i) we determine that such assets are not critical to our strategy or (ii) we believe the opportunity to monetize the asset is attractive or for various other reasons, including for the reduction of indebtedness. We have explored and will continue to explore the sale of certain non-core assets. Although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories. As a result, any such sale could have an adverse effect on our business, prospects and opportunities for growth, financial condition, results of operations, cash flows, and/or share price.

WE AND NEW MYLAN HAVE SIGNIFICANT INDEBTEDNESS WHICH COULD ADVERSELY AFFECT OUR FINANCIAL POSITION AND PREVENT US FROM FULFILLING OUR OBLIGATIONS UNDER SUCH INDEBTEDNESS. ANY REFINANCING OF THIS DEBT COULD BE AT SIGNIFICANTLY HIGHER INTEREST RATES. OUR AND NEW MYLAN'S SUBSTANTIAL INDEBTEDNESS COULD LEAD TO ADVERSE CONSEQUENCES.

Our and New Mylan's level of indebtedness could have important consequences, including but not limited to:

- increasing our vulnerability to general adverse economic and industry conditions; requiring us to dedicate a substantial portion of our cash flow from operations to make debt service payments, thereby reducing the availability of cash flow to fund working capital, capital expenditures, acquisitions and investments and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, challenges and opportunities, and changes in our businesses and the markets in which we operate;
- limiting our ability to obtain additional financing to fund our working capital, capital expenditures, acquisitions and debt service requirements and other financing needs;
- increasing our vulnerability to increases in interest rates in general because a substantial portion of our indebtedness bears interest at floating rates; and
- placing us at a competitive disadvantage to our competitors that have less debt.

Our and New Mylan's ability to service our indebtedness will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we and New Mylan do not have sufficient cash flow to service our indebtedness, we and New Mylan may need to refinance all or part of our existing indebtedness, borrow more money or sell securities or assets, some or all of which may not be available to us at acceptable terms or at all. In addition, we and New Mylan may need to incur additional indebtedness in the future in the ordinary course of business. Although the terms of our senior credit agreement and our bond indentures allow us to incur additional debt, this is subject to certain limitations which may preclude us from incurring the amount of indebtedness we otherwise desire.

In addition, if we and New Mylan incur additional debt, the risks described above could intensify. If global credit markets return to their recent levels of contraction, future debt financing may not be available to us when required or may not be available on acceptable terms, and as a result we may be unable to grow our business, take advantage of business opportunities, respond to competitive pressures or satisfy our obligations under our indebtedness. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

Our credit facilities, senior unsecured notes, accounts receivable securitization facility, other outstanding indebtedness and any additional indebtedness we incur in the future impose, or may impose, significant operating and financial restrictions on us. These restrictions limit our ability to, among other things, incur additional indebtedness, make investments, pay certain dividends, prepay other indebtedness, sell assets, incur certain liens, enter into agreements

with our affiliates or restricting our subsidiaries' ability to pay dividends, merge or consolidate. In addition, our Revolving Credit Agreement, Term Credit Agreement and accounts receivable securitization facility require us to maintain specified financial ratios. A breach of any of these covenants or our inability to maintain the required financial ratios could result in a default under the related indebtedness. If a default occurs, the relevant lenders could elect to declare our indebtedness, together with accrued interest and other fees, to

be immediately due and payable. These factors could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THE TOTAL AMOUNT OF INDEBTEDNESS RELATED TO OUR OUTSTANDING CASH CONVERTIBLE NOTES DUE 2015 (THE "CASH CONVERTIBLE NOTES") WILL INCREASE IF NEW MYLAN'S STOCK PRICE INCREASES. ALSO, WE HAVE ENTERED INTO HEDGES AND WARRANT TRANSACTIONS IN CONNECTION WITH THE CASH CONVERTIBLE NOTES IN ORDER TO HEDGE SOME OF THE RISK ASSOCIATED WITH THE POTENTIAL INCREASE OF INDEBTEDNESS AND SETTLEMENT VALUE. SUCH TRANSACTIONS HAVE BEEN CONSUMMATED WITH CERTAIN COUNTERPARTIES, MAINLY HIGHLY RATED FINANCIAL INSTITUTIONS. ANY INCREASE IN INDEBTEDNESS, NET EXPOSURE RELATED TO THE RISK OR FAILURE OF ANY COUNTERPARTIES TO PERFORM THEIR OBLIGATIONS, COULD HAVE ADVERSE EFFECTS ON US, INCLUDING UNDER OUR DEBT AGREEMENTS.

Prior to the consummation of the Transaction, the value of the total amount of indebtedness related to our Cash Convertible Notes was based on our share price. In connection with the consummation of the Transaction, we and New Mylan executed a supplemental indenture that amended the indenture governing the Cash Convertible Notes so that, among other things, all relevant determinations for purposes of the cash conversion rights to which holders may be entitled from time to time in accordance with such indenture shall be made by reference to the New Mylan ordinary shares. From and after the consummation of the Transaction, the value of the total amount of indebtedness related to our Cash Convertible Notes will be based on New Mylan's share price. Under applicable accounting rules, the cash conversion feature that is a term of the Cash Convertible Notes must be recorded as a liability on our balance sheet and periodically marked to fair value. If New Mylan's stock price increases, the liability associated with the cash conversion feature would increase and, because this liability must be periodically marked to fair value on our balance sheet, the total amount of indebtedness related to the notes that is shown on our balance sheet would also increase. This could have adverse effects on us, including under any future debt agreements that contain covenants based on a definition of total indebtedness as defined under U.S. GAAP. As a result, we may not be able to comply with such covenants in the future, which could, among other things, restrict our ability to grow our business, take advantage of business opportunities or respond to competitive pressures. The occurrence of any of the above risks could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

In connection with the issuance of the Cash Convertible Notes, we entered into convertible note hedge and warrant transactions with certain financial institutions, each of which we refer to as a counterparty. In connection with the consummation of the Transaction, the terms of the convertible note hedge were adjusted so that the cash settlement value will be based on New Mylan ordinary shares. The terms of the warrant transactions were also adjusted so that, from and after the consummation of the Transaction, we may settle the obligations under the warrant transaction by delivering New Mylan ordinary shares. The cash convertible note hedge is comprised of purchased cash-settled call options that are expected to reduce our exposure to potential cash payments required to be made by us upon the cash conversion of the Cash Convertible Notes. We have also entered into respective warrant transactions with the counterparties pursuant to which, as amended, we will have sold to each counterparty warrants for the purchase of shares of New Mylan's ordinary shares. Together, each of the convertible note hedges and warrant transactions are expected to provide us with some protection against increases in New Mylan's stock price over the conversion price per share. However, there is no assurance that these transactions will remain in effect at all times. Also, although we believe the counterparties are highly rated financial institutions, there are no assurances that the counterparties will be able to perform their respective obligations under the agreement we have with each of them. Any net exposure related to conversion of the notes or any failure of the counterparties to perform their obligations under the agreements we have with them could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE ENTER INTO VARIOUS AGREEMENTS IN THE NORMAL COURSE OF BUSINESS WHICH PERIODICALLY INCORPORATE PROVISIONS WHEREBY WE INDEMNIFY THE OTHER PARTY TO THE AGREEMENT.

In the normal course of business, we periodically enter into employment, legal settlement, and other agreements which incorporate indemnification provisions. In some but not all cases, we maintain insurance coverage which we believe will effectively mitigate our obligations under certain of these indemnification provisions. However, should our obligation under an indemnification provision exceed any applicable coverage or should coverage be denied, our business, financial condition, results of operations, cash flows, and/or share price could be materially adversely affected.

CURRENCY FLUCTUATIONS AND CHANGES IN EXCHANGE RATES COULD ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR SHARE PRICE.

Although we report our financial results in U.S. Dollars, a significant portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including among others the Euro, Indian Rupee, British Pound, Canadian Dollar, Japanese Yen, Australian Dollar and Brazilian Real. Our results of operations and, in some cases, cash flows, have in the past been and may in the future be adversely affected by certain movements in currency exchange rates. In particular, the risk of a debt default by one or more European countries and related European or national financial restructuring efforts may cause volatility in the value of the Euro. Defaults or restructurings in other countries could have a similar adverse impact. From time to time, we may implement currency hedges intended to reduce our exposure to changes in foreign currency exchange rates. However, our hedging strategies may not be successful, and any of our unhedged foreign exchange exposures will continue to be subject to market fluctuations. The occurrence of any of the above risks could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THERE ARE INHERENT UNCERTAINTIES INVOLVED IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED IN THE PREPARATION OF FINANCIAL STATEMENTS IN ACCORDANCE WITH U.S. GAAP. ANY FUTURE CHANGES IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED OR NECESSARY REVISIONS TO PRIOR ESTIMATES, JUDGMENTS OR ASSUMPTIONS OR CHANGES IN ACCOUNTING STANDARDS COULD LEAD TO A RESTATEMENT OR REVISION TO PREVIOUSLY ISSUED FINANCIAL STATEMENTS.

The Consolidated and Condensed Consolidated Financial Statements included in the periodic reports we file with the SEC are prepared in accordance with U.S. GAAP. The preparation of financial statements in accordance with U.S. GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets, liabilities, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE MUST MAINTAIN ADEQUATE INTERNAL CONTROLS AND BE ABLE, ON AN ANNUAL BASIS, TO PROVIDE AN ASSERTION AS TO THE EFFECTIVENESS OF SUCH CONTROLS.

Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports. We spend a substantial amount of management and other employee time and resources to comply with laws, regulations and standards relating to corporate governance and public disclosure. In the U.S., such regulations include the Sarbanes-Oxley Act of 2002, SEC regulations and the NASDAQ listing standards. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 (“Section 404”) requires management’s annual review and evaluation of our internal control over financial reporting and attestation as to the effectiveness of these controls by our independent registered public accounting firm. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting. Additionally, internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, this could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

OUR FUTURE SUCCESS IS HIGHLY DEPENDENT ON OUR CONTINUED ABILITY TO ATTRACT AND RETAIN KEY PERSONNEL. LOSS OF KEY PERSONNEL COULD LEAD TO LOSS OF CUSTOMERS, BUSINESS DISRUPTION, AND A DECLINE IN REVENUES, ADVERSELY AFFECT THE PROGRESS OF PIPELINE PRODUCTS, OR OTHERWISE ADVERSELY AFFECT OUR OPERATIONS.

It is important that we attract and retain qualified personnel in order to develop and commercialize new products, manage the business, and compete effectively. Competition for qualified personnel in the pharmaceutical industry is very intense. If we fail to attract and retain key scientific, technical, commercial, or management personnel, our business could be affected adversely. Additionally, while we have employment agreements with certain key employees in place, their employment for the duration of the agreement is not guaranteed. Current and prospective employees might also experience uncertainty about

their future roles with us following the consummation of the Transaction, which might adversely affect our ability to retain key managers and other employees. If we are unsuccessful in retaining our key employees or enforcing certain post-employment contractual provisions such as confidentiality or non-competition, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE ARE IN THE PROCESS OF ENHANCING AND FURTHER DEVELOPING OUR GLOBAL ENTERPRISE RESOURCE PLANNING SYSTEMS AND ASSOCIATED BUSINESS APPLICATIONS, WHICH COULD RESULT IN BUSINESS INTERRUPTIONS IF WE ENCOUNTER DIFFICULTIES.

We are enhancing and further developing our global enterprise resource planning (“ERP”) and other business critical information technology (“IT”) infrastructure systems and associated applications to provide more operating efficiencies and effective management of our business and financial operations. Such changes to ERP systems and related software, and other IT infrastructure carry risks such as cost overruns, project delays and business interruptions and delays. If we experience a material business interruption as a result of our ERP enhancements, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

WE ARE INCREASINGLY DEPENDENT ON INFORMATION TECHNOLOGY AND OUR SYSTEMS AND INFRASTRUCTURE FACE CERTAIN RISKS, INCLUDING CYBERSECURITY AND DATA LEAKAGE RISKS.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. We are increasingly dependent on sophisticated information technology systems and infrastructure to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, some of which are outside the U.S., including significant elements of our information technology infrastructure, and as a result we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. We and our vendors could be susceptible to third party attacks on our information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, “hackers” and others. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. However, such information can be difficult to protect. While we have taken steps to protect such information and invested heavily in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

THE EXPANSION OF SOCIAL MEDIA PLATFORMS PRESENT NEW RISKS AND CHALLENGES.

The inappropriate use of certain social media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection and/or dissemination of personally identifiable information. In addition, negative posts or comments about us on any social networking web site could seriously damage our reputation. Further, the disclosure of non-public company sensitive information through external media channels could lead to information loss as there might not be structured processes in place to secure and protect information. If

our non-public sensitive information is disclosed or if our reputation is seriously damaged through social media, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

For information regarding properties, refer to Item 1, "Business," in Part I of this Annual Report.

ITEM 3. Legal Proceedings

For information regarding legal proceedings, refer to Note 14, "Contingencies," in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

On February 27, 2015, Mylan became an indirect wholly owned subsidiary of New Mylan, and Mylan's common stock ceased trading on the NASDAQ Stock Market. New Mylan's ordinary shares began trading on the NASDAQ Stock Market under the symbol "MYL" on March 2, 2015. The following table sets forth the quarterly high and low sales prices for our common stock for the periods indicated:

Year Ended December 31, 2014	High	Low
Three months ended March 31, 2014	\$57.52	\$41.97
Three months ended June 30, 2014	55.30	44.74
Three months ended September 30, 2014	53.05	44.80
Three months ended December 31, 2014	59.60	45.02
Year Ended December 31, 2013	High	Low
Three months ended March 31, 2013	\$31.22	\$27.38
Three months ended June 30, 2013	32.27	27.66
Three months ended September 30, 2013	39.41	30.01
Three months ended December 31, 2013	44.73	36.97

As of February 24, 2015, there were approximately 159,174 shareholders of Mylan Inc. common stock, including those held in street or nominee name. On February 27, 2015, 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.

Mylan did not pay dividends in 2014 and New Mylan does not intend to pay dividends on its ordinary shares in the near future.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On October 29, 2013, the Company announced that its Board of Directors had approved the repurchase of up to \$500 million of the Company's common stock in the open market or through other methods. The repurchase of approximately 12.2 million shares for \$500 million was completed by December 31, 2013.

In the past three years, we have issued unregistered securities in connection with the following transactions: In June 2013, we issued \$1.15 billion aggregate principal amount of 1.800% Senior Notes due 2016 and 2.600% Senior Notes due 2018 in a private offering exempt from the registration requirements of the Securities Act to qualified institutional buyers in accordance with Rule 144A and to persons outside of the United States pursuant to Regulation S under the Securities Act. The Company filed a registration statement with the SEC with respect to an offer to exchange these notes for registered notes with the same aggregate principal amount and terms substantially identical in all material respects.

In December 2012, we issued \$750.0 million aggregated principal amount of 3.125% Senior Notes due 2023. These notes were issued in a private offering exempt from the registration requirements of the Securities Act to qualified institutional buyers in accordance with Rule 144A and to persons outside of the United States pursuant to Regulation S under the Securities Act.

STOCK PERFORMANCE GRAPH

Set forth below is a performance graph comparing the cumulative total return (assuming reinvestment of dividends), in U.S. Dollars, for the calendar years ended December 31, 2010, 2011, 2012, 2013 and 2014 of \$100 invested on December 31, 2009 in Mylan's Common Stock, the Standard & Poor's 500 Index and the Dow Jones U.S. Pharmaceuticals Index.

	12/09	12/10	12/11	12/12	12/13	12/14
Mylan Inc.	100.00	114.65	116.44	148.94	235.49	305.86
S&P 500	100.00	115.06	117.49	136.30	180.44	205.14
Dow Jones U.S. Pharmaceuticals	100.00	102.13	121.17	138.01	184.83	224.39

ITEM 6. Selected Financial Data

The selected consolidated financial data set forth below should be read in conjunction with “Management’s Discussion and Analysis of Results of Operations and Financial Condition” and the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included in Item 8 in this Form 10-K. The functional currency of the primary economic environment in which the operations of Mylan and its subsidiaries in the U.S. are conducted is the U.S. Dollar. The functional currency of non-U.S. subsidiaries is generally the local currency in the country in which each subsidiary operates.

(In millions, except per share amounts)	Year Ended December 31,				
	2014	2013	2012	2011 ⁽¹⁾	2010
Statements of Operations:					
Total revenues	\$7,719.6	\$6,909.1	\$6,796.1	\$6,129.8	\$5,450.5
Cost of sales ⁽²⁾	4,191.6	3,868.8	3,887.8	3,566.4	3,233.1
Gross profit	3,528.0	3,040.3	2,908.3	2,563.4	2,217.4
Operating expenses:					
Research and development	581.8	507.8	401.3	294.7	282.1
Selling, general and administrative	1,625.7	1,408.5	1,392.4	1,214.6	1,086.6
Litigation settlements, net	47.9	(14.6)	(3.1)	48.6	127.1
Other operating (income) expense, net	(80.0)	3.1	8.3	—	—
Earnings from operations	1,352.6	1,135.5	1,109.4	1,005.5	721.6
Interest expense	333.2	313.3	308.7	335.9	331.5
Other expense (income), net	44.9	74.9	(3.5)	15.0	34.2
Earnings before income taxes and noncontrolling interest	974.5	747.3	804.2	654.6	355.9
Income tax provision	41.4	120.8	161.2	115.8	10.4
Net earnings attributable to the noncontrolling interest	(3.7)	(2.8)	(2.1)	(2.0)	(0.4)
Net earnings attributable to Mylan Inc. before preferred dividends	929.4	623.7	640.9	536.8	345.1
Preferred dividends	—	—	—	—	121.5
Net earnings attributable to Mylan Inc. common shareholders	\$929.4	\$623.7	\$640.9	\$536.8	\$223.6
Selected Balance Sheet data:					
Total assets	\$15,886.6	\$15,294.8	\$11,931.9	\$11,598.1	\$11,536.8
Working capital ⁽³⁾	1,481.2	1,507.1	1,709.2	1,005.7	1,749.8
Short-term borrowings	330.7	439.8	299.0	128.1	162.5
Long-term debt, including current portion of long-term debt	8,138.5	7,586.5	5,431.9	5,168.2	5,268.2
Total equity	3,276.0	2,959.9	3,355.8	3,504.8	3,615.4
Earnings per common share attributable to Mylan Inc. common shareholders:					
Basic	\$2.49	\$1.63	\$1.54	\$1.25	\$0.69
Diluted	\$2.34	\$1.58	\$1.52	\$1.22	\$0.68
Weighted average common shares outstanding:					
Basic	373.7	383.3	415.2	430.8	324.5
Diluted	398.0	394.5	420.2	438.8	329.0

(1)The weighted average common shares outstanding includes the full year effect of the conversion of the 6.50% mandatorily convertible preferred stock into approximately 125.2 million shares of common stock.

(2)Cost of sales includes the following amounts primarily related to the amortization of purchased intangibles from acquisitions: \$391.3 million, \$353.1 million, \$349.5 million, \$348.6 million and \$309.2 million for 2014, 2013, 2012, 2011 and 2010, respectively. In addition, cost of sales included the following amounts related to impairment charges to intangible assets: \$27.7 million, \$18.0 million, \$41.6 million and \$16.2 million in 2014, 2013, 2012 and 2011, respectively.

(3)Working capital is calculated as current assets minus current liabilities.

ITEM 7. Management's Discussion and Analysis of Financial Condition And Results of Operations

The following discussion and analysis addresses material changes in the financial condition and results of operations of Mylan Inc. and subsidiaries (the "Company," "Mylan," "our" or "we") for the periods presented. This discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the related Notes to Consolidated Financial Statements and our other Securities and Exchange Commission ("SEC") filings and public disclosures.

This Form 10-K contains "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about the acquisition (the "Abbott Transaction") by Mylan N.V. ("New Mylan") of both Mylan and Abbott Laboratories' ("Abbott") non-U.S. developed markets specialty and branded generics business (the "Business"), benefits and synergies of the Transaction, future opportunities for Mylan or New Mylan and products, and any other statements regarding Mylan's or New Mylan's future operations, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competition, and other expectations and targets for future periods. These may often be identified by the use of words such as "will," "may," "could," "should," "would," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "intend," "continue," "target" and variations of the comparable words. Because forward-looking 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: the ability to meet expectations regarding the accounting and tax treatments of the Transaction; changes in relevant tax and other laws, including but not limited to changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; the integration of the Business being more difficult, time-consuming, or costly than expected; operating costs, customer loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients, or suppliers) being greater than expected following the Transaction; the retention of certain key employees of the Business being difficult; the possibility that Mylan and New Mylan may be unable to achieve expected synergies and operating efficiencies in connection with the Transaction within the expected time-frames or at all and to successfully integrate the Business; expected or targeted future financial and operating performance and results; the capacity to bring new products to market, including but not limited to where Mylan or New Mylan uses its business judgment and decides to manufacture, market, and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an "at-risk launch"); success of clinical trials and our ability to execute on new product opportunities; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on financial condition, results of operations and/or cash flows; the ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; the impacts of competition; changes in the economic and financial conditions of the business of Mylan or New Mylan; the inherent challenges, risks, and costs in identifying, acquiring, and integrating complementary or strategic acquisitions of other companies, products or assets and in achieving anticipated synergies; uncertainties and matters beyond the control of management; and inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with U.S. GAAP and related standards or on an adjusted basis. For more detailed information on the risks and uncertainties associated with Mylan's business activities, see the risks described in this Annual Report on Form 10-K for the year ended December 31, 2014 and our and New Mylan's other filings with the SEC. These risks, as well as other risks associated with Mylan, New Mylan, the Business, and the Transaction are also more fully discussed in the Registration Statement on Form S-4 that New Moon B.V. (referred to herein as New Mylan) filed with the SEC on November 5, 2014, as amended on December 9, 2014, and as further amended on December 23, 2014, and in the proxy statement Mylan filed with the SEC on December 24, 2014, as well as the prospectus New Mylan filed with the SEC on December 24, 2014. You can access Mylan's and New Mylan's filings with the SEC through the SEC website at www.sec.gov, and the Company strongly encourages you to do so. The Company undertakes no obligation to update any statements herein for revisions or changes after the date of this

Form 10-K.

Executive Overview

Mylan 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 Transaction, Mylan has expanded its global footprint to reach customers in approximately 145 countries and territories. We operate a global, high quality vertically-

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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.

Mylan has two segments, "Generics" and "Specialty." Generics primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule, injectable or transdermal patch form, as well as API.

Our generic pharmaceutical business is conducted primarily in the United States ("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 Laboratories Limited ("Mylan India"), which is included within Rest of World in our Generics segment. Specialty engages mainly in the manufacture and sale of branded specialty injectable and nebulized products. We also report in Corporate/Other certain R&D expenses, general and administrative expenses, litigation settlements, amortization of intangible assets and certain purchase accounting items, impairment charges, if any, and other items not directly attributable to the segments.

Significant recent events include the following:

Abbott Branded Generics Business

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 after 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.

In accordance with U.S. GAAP, New Mylan will use the purchase method of accounting to account for this Transaction with Mylan being treated as the accounting acquirer.

Agila Specialties

On February 27, 2013, the Company announced that it signed definitive agreements to acquire Agila Specialties businesses ("Agila"), a developer, manufacturer and marketer of high-quality generic injectable products, from Strides Arcolab Limited ("Strides Arcolab"). The transaction closed on December 4, 2013, and the total purchase price was

approximately \$1.43 billion (net of cash acquired of \$3.4 million), which included estimated contingent consideration of \$250 million. During the three months ended September 30, 2014, the Company entered into an agreement with Strides Arcolab to settle a portion of the contingent consideration for \$150 million, for which the Company had accrued \$230 million at the acquisition date. As a result of this agreement, the Company recognized a gain of \$80 million during the year ended December 31, 2014, which is included in other operating (income) expense, net in the Consolidated Statements of Operations.

The remaining contingent consideration, which could total a maximum of \$211 million, is primarily related to the satisfaction of certain regulatory conditions, including potential regulatory remediation costs and the resolution of certain pre-acquisition contingencies. The acquisition of Agila significantly expanded and strengthened Mylan's injectables platform and portfolio, and also provided Mylan entry into certain new geographic markets.

Other Transactions

On February 2, 2015, the Company signed a definitive agreement to acquire certain female health care businesses from Famy Care Limited (“Famy Care”), a specialty women’s health care company with global leadership in generic oral contraceptive products. The purchase price is \$750 million in cash plus additional contingent payments of up to \$50 million. The transaction is expected to close in the second half of 2015, subject to regulatory approvals and certain closing conditions.

On January 30, 2015, the Company entered into a development and commercialization collaboration with Theravance Biopharma, Inc. (“Theravance Biopharma”) for the development and, subject to U.S. Food and Drug Administration (“FDA”) approval, commercialization of TD-4208, a novel once-daily nebulized long-acting muscarinic antagonist (“LAMA”) for chronic obstructive pulmonary disease (“COPD”) and other respiratory diseases. Under the terms of the agreement, Mylan and Theravance Biopharma will co-develop nebulized TD-4208 for COPD and other respiratory diseases. Theravance Biopharma will lead the U.S. registrational development program and Mylan will be responsible for reimbursement of Theravance Biopharma’s costs for that program up until the approval of the first new drug application, after which costs will be shared. In addition, Mylan will be responsible for commercial manufacturing. In the U.S., Mylan will lead commercialization and Theravance Biopharma will retain the right to co-promote the product under a profit-sharing arrangement. In addition to funding the U.S. registrational development program, Mylan will pay Theravance Biopharma an initial payment of \$15 million in the second quarter of 2015 and made a \$30 million equity investment in Theravance Biopharma. Under the terms of the agreement, Theravance Biopharma is eligible to receive potential development and sales milestone payments totaling \$220 million in the aggregate.

On September 10, 2014, the Company entered into an agreement with Aspen Global Incorporated to acquire the U.S. commercialization, marketing and intellectual property rights related to Arixtra® Injection (“Arixtra”) and the authorized generic rights of Arixtra. The purchase price for this intangible asset was \$300 million, of which \$225 million was paid at the closing of the transaction on September 25, 2014. An additional \$37.5 million was paid during the fourth quarter of 2014. The remaining \$37.5 million is held in escrow and will be released upon satisfaction of certain conditions.

Senior Credit Facilities and Issuance of Senior Notes

In December 2014, the Company entered into a new Revolving Credit Agreement with a syndication of lenders, which contains a \$1.5 billion revolving facility (the “New Revolving Facility”). The New Revolving Facility includes a \$150 million subfacility for the issuance of letters of credit and a \$125 million subfacility for swingline borrowings. Amounts drawn on the New Revolving Facility become due and payable on December 19, 2019.

In December 2014, the Company also entered into a new Term Credit Agreement with a syndicate of banks which provided an \$800 million term loan (“2014 Term Loan”). The 2014 Term Loan matures on December 19, 2017 and has no required amortization payments. The proceeds of the 2014 Term Loan were used for working capital expenditures and to repay outstanding borrowings under the Company’s credit agreement entered into in June 2013 (the “June 2013 Credit Agreement”). Borrowings under the June 2013 Credit Agreement were used to fund the redemption of the November 2018 Senior Notes.

In January 2015, Mylan Securitization LLC (“Mylan Securitization”) entered into a new accounts receivable securitization facility with a group of financial institutions and commercial paper conduits sponsored by financial institutions (the “Receivables Facility”). The Receivables Facility has a committed balance of \$400 million, although from time-to-time, the available amount of the Receivables Facility may be less than \$400 million based on accounts receivable concentration limits and other eligibility requirements. The Receivables Facility matures in January 2018.

In November 2013, we issued \$2.0 billion aggregate principal amount of registered Senior Notes, comprised of 1.350% Senior Notes due 2016, 2.550% Senior Notes due 2019, 4.200% Senior Notes due 2023 and 5.400% Senior Notes due 2043. The net proceeds from the offering were used to fund the acquisition of Agila and for general corporate purposes, including, but not limited to, the repayment of short-term borrowings and funding of the share repurchase program executed in the fourth quarter of 2013.

In June 2013, we issued \$1.15 billion aggregate principal amount of 1.800% Senior Notes due 2016 and 2.600% Senior Notes due 2018 (“June 2013 Senior Notes”) in a private offering exempt from the registration requirements of the Securities Act to qualified institutional buyers in accordance with Rule 144A and to persons outside of the United States pursuant to Regulation S under the Securities Act. The Company filed a registration statement with the SEC with respect to an offer to exchange these notes for registered notes with the same aggregate principal amount and terms substantially identical in all material respects. This registration statement was declared effective on January 31, 2014 and the exchange offer was

completed on March 4, 2014. Net proceeds from the June 2013 Senior Notes were used to repay all of its outstanding \$1.13 billion 2011 Term Loans and for general corporate purposes.

Financial Summary

For the year ended December 31, 2014, Mylan reported total revenues of \$7.72 billion compared to \$6.91 billion for the year ended December 31, 2013. This represents an increase in revenues of \$810.5 million, or 11.7%. Consolidated gross profit for the current year was \$3.53 billion, compared to \$3.04 billion in the prior year, an increase of \$487.7 million, or 16.0%. For the current year, earnings from operations were \$1.35 billion, as compared to \$1.14 billion for the year ended December 31, 2013, an increase of \$217.1 million, or 19.1%.

Net earnings attributable to Mylan Inc. common shareholders increased \$305.7 million, or 49.0%, to \$929.4 million for the year ended December 31, 2014 compared to \$623.7 million for the prior year. Diluted earnings per common share attributable to Mylan Inc. increased 48.1% from \$1.58 to \$2.34 for the year ended December 31, 2014 compared to the prior year.

A detailed discussion of the Company's financial results can be found below in the section titled "Results of Operations." As part of this discussion, we also report sales performance using the non-GAAP financial measure of "constant currency" sales. This measure provides information on the change in net sales assuming that foreign currency exchange rates had not changed between the prior and current period. The comparisons presented at constant currency rates reflect comparative local currency sales at the prior year's foreign exchange rates. We routinely evaluate our third party net sales performance at constant currency so that sales results can be viewed without the impact of foreign currency exchange rates, thereby facilitating a period-to-period comparison of our operational activities, and believe that this presentation also provides useful information to investors for the same reason. The following table compares third party net sales on an actual and constant currency basis for each reportable segment and the geographic regions within the Generics segment for the years ended December 31, 2014, 2013 and 2012.

	Year Ended December 31,			2014 Percent Change		2013 Percent Change			
	2014	2013	2012	Actual	Constant Currency	Actual	Constant Currency		
Generics:									
Third party net sales									
North America	\$3,361.2	\$3,006.6	\$3,225.4	12	% 12	% (7)% (7)%	
Europe	1,476.8	1,429.7	1,297.6	3	% 3	% 10	% 8	%	
Rest of World	1,621.3	1,438.6	1,391.9	13	% 18	% 3	% 14	%	
Total third party net sales	6,459.3	5,874.9	5,914.9	10	% 11	% (1)% 1	%	
Other third party revenues	51.1	25.8	31.3						
Total third party revenues	6,510.4	5,900.7	5,946.2						
Intersegment sales	4.7	5.7	3.1						
Generics total revenues	6,515.1	5,906.4	5,949.3						
Specialty:									
Third party net sales	1,187.2	981.7	835.4	21	% 21	% 18	% 18	%	
Other third party revenues	22.0	26.8	14.6						
Total third party revenues	1,209.2	1,008.5	850.0						
Intersegment sales	9.0	19.3	37.0						
Specialty total revenues	1,218.2	1,027.8	887.0						
Elimination of intersegment sales	(13.7) (25.1) (40.2)					
Consolidated total revenues	\$7,719.6	\$6,909.1	\$6,796.1	12	% 13	% 2	% 3	%	

More information about other non-GAAP measures used by the Company as part of this discussion, including Adjusted Cost of Sales, Adjusted Gross Margins, Adjusted Earnings and Adjusted EPS can be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Use of Non-GAAP Financial Measures."

Results of Operations

2014 Compared to 2013

Total Revenues and Gross Profit

For the year ended December 31, 2014, Mylan reported total revenues of \$7.72 billion compared to \$6.91 billion in the prior year. Total revenues include both net sales and other revenues from third parties. Third party net sales for the current year were \$7.65 billion compared to \$6.86 billion for the prior year, representing an increase of \$789.9

million, or 11.5%. Other

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third party revenues for the current year were \$73.1 million compared to \$52.5 million in the prior year, an increase of \$20.6 million.

Mylan's current year revenues were unfavorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in India, Japan, Australia and Canada. The unfavorable impact of foreign currency translation on current year total revenues was approximately \$86 million, or 1%. As such, constant currency total revenues increased approximately \$897 million, or 13%. The increase in constant currency total revenues was the result of double digit third party net sales growth in the Specialty and Generics segments, which included growth in all regions. The contribution from new products, and to a lesser extent, net sales from acquired businesses, totaled approximately \$593 million in 2014. Constant currency net sales from existing products increased approximately \$283 million as a result of constant currency increases in volume of approximately \$203 million and in pricing of approximately \$80 million.

In arriving at net sales, gross sales are reduced by provisions for estimates, including discounts, rebates, promotions, price adjustments, returns and chargebacks. See the section titled Application of Critical Accounting Policies in this Item 7, for a discussion of our methodology with respect to such provisions. For 2014, the most significant amounts charged against gross sales were \$3.47 billion related to chargebacks and \$1.55 billion related to incentives offered to our direct customers, such as promotions and volume related incentives. For 2013, the most significant amounts charged against gross sales were for chargebacks in the amount of \$2.35 billion and incentives offered to our direct customers in the amount of \$1.64 billion.

Cost of sales for the year ended December 31, 2014 was \$4.19 billion, compared to \$3.87 billion in the prior year. Cost of sales for the current year was impacted by the amortization of acquired intangible assets of approximately \$403.6 million and restructuring and other special items of approximately \$113.7 million as described further in the section titled "Use of Non-GAAP Financial Measures." The prior year comparable period cost of sales included similar purchase accounting related amortization of approximately \$369.1 million and restructuring and other special items of approximately \$54.7 million. The increase in current year purchase accounting related amortization and restructuring and other special items is principally the result of increased acquisition related costs and amortization expense as a result of the Agila acquisition, which was completed in late 2013. Excluding purchase accounting related amortization and restructuring and other special items, Adjusted Cost of Sales in the current year increased to \$3.67 billion from \$3.45 billion, corresponding to the increase in net sales.

Gross profit for the current year was \$3.53 billion and gross margins were 45.7%. For 2013, gross profit was \$3.04 billion, and gross margins were 44.0%. Excluding the purchase accounting related amortization and restructuring and other special items discussed in the paragraph above, Adjusted Gross Margins were approximately 52% and 50% in 2014 and 2013, respectively. Adjusted Gross Margins were favorably impacted in the current year as a result of new product introductions by approximately 180 basis points and favorable pricing and volume on the EpiPen® Auto-Injector in our Specialty segment by approximately 45 basis points. These increases were partially offset by lower pricing on existing products within the Generics segment.

From time to time, a limited number of our products may represent a significant portion of our net sales, gross profit and net earnings. Generally, this is due to the timing of new product launches and the amount, if any, of additional competition in the market. Our top ten products in terms of sales, in the aggregate, represented approximately 33% and 31% of the Company's total revenues in 2014 and 2013, respectively.

Generics Segment

For the current year, Generics third party net sales were \$6.46 billion compared to \$5.87 billion in the prior year, an increase of \$584.5 million, or 9.9%. Foreign currency had an unfavorable impact on third party net sales for the current year. Generics constant currency third party net sales for the current year increased by approximately \$671

million, or 11% when compared to the prior year.

Third party net sales from North America were \$3.36 billion for the current year, compared to \$3.01 billion for the prior year, representing an increase of \$354.6 million, or 11.8%. The increase in current year third party net sales was principally due to net sales from new products, and to a lesser extent, net sales from acquired businesses totaling approximately \$480 million. This increase was partially offset by lower volumes on existing products. The effect of foreign currency translation was insignificant within North America.

Products generally contribute most significantly to revenues and gross margins at the time of their launch, even more so in periods of market exclusivity, or in periods of limited generic competition. As such, the timing of new product introductions can have a significant impact on the Company's financial results. The entrance into the market of additional

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competition generally has a negative impact on the volume and pricing of the affected products. Additionally, pricing is often affected by factors outside of the Company's control.

Third party net sales from Europe were \$1.48 billion in 2014, compared to \$1.43 billion in 2013, an increase of \$47.1 million, or 3.3%. This increase was the result of increased volumes in France, Italy and the United Kingdom ("U.K.") as well as new product net sales. Partially offsetting this increase was lower pricing in a number of European markets in which Mylan operates, as a result of government-imposed pricing reductions and competitive market conditions. The effect of foreign currency translation was insignificant within Europe.

Local currency third party net sales from Mylan's businesses in France, Italy and the U.K. increased compared to the prior year as a result of new product launches and higher volumes on existing products partially offset by the impact of lower pricing due to government-imposed pricing reductions and an increasingly competitive market. Our market share in France remained relatively stable in 2014 as compared to 2013, and we remain the market leader.

In addition to France, Italy and the U.K., certain other markets in which we do business, including Spain, have undergone government-imposed price reductions, and further government-imposed price reductions are expected in the future. Such measures, along with the tender systems discussed below, are likely to have a negative impact on revenues and gross profit in these markets. However, government initiatives in certain markets that appear to favor generic products could help to mitigate this unfavorable effect by increasing rates of generic substitution and penetration.

A number of markets in which we operate have implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Generally speaking, tender systems can have an unfavorable impact on revenue and profitability. Under such tender systems, manufacturers submit bids that establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Additionally, the loss of a tender by a third party to whom we supply API can also have a negative impact on our sales and profitability. Sales, primarily in Germany, continue to be negatively affected by the impact of tender systems.

In Rest of World, third party net sales were \$1.62 billion in 2014, compared to \$1.44 billion in 2013, an increase of \$182.7 million, or 12.7%. Rest of World constant currency third party net sales increased by approximately \$260 million, or 18%. This increase was primarily driven by higher third party net sales by our operations in India as a result of strong growth in the antiretroviral ("ARV") franchise, as well as constant currency growth in Japan. Sales were also positively impacted by increases in net sales from new products and acquired businesses.

The increase in third party net sales from our operations in India is due to significant growth in sales of finished dosage form ("FDF") ARV products used in the treatment of HIV/AIDS. In addition to third party net sales, Rest of World region also supplies both FDF generic products and API to Mylan subsidiaries in conjunction with the Company's vertical integration strategy. Intercompany sales recognized by Rest of World region were \$714.0 million in 2014, compared to \$678.3 million in the prior year. These intercompany sales eliminate within, and therefore are not included in Generics or consolidated third party net sales.

In Japan, third party net sales increased as a result of new product introductions. The Company continues to see Japan as a key region for future sales growth as the market expands. In Australia, local currency third party net sales decreased versus the prior year as a result of significant government-imposed pricing reform and reduced volumes, partially offset by new product sales. As in Europe, both Australia and Japan have undergone government-imposed price reductions which have had, and could continue to have, a negative impact on sales and gross profit in these markets.

Specialty Segment

For the current year, Specialty reported third party net sales of \$1.19 billion, an increase of \$205.5 million, or 20.9%, from the prior year of \$981.7 million. The increase was principally the result of higher sales of the EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions (anaphylaxis), as a result of favorable pricing and increased volume. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and, in 2014 it became the first Mylan product to reach \$1 billion in annual net sales. The market continues to grow as awareness of the risk of anaphylaxis increases. In addition, sales of the Perforomist® Inhalation Solution increased by double digits from the prior year as a result of favorable pricing.

Operating Expenses

Research & Development Expense

R&D expense in 2014 was \$581.8 million, compared to \$507.8 million in the same prior year period, an increase of \$74.0 million. R&D increased primarily due to the continued development of our respiratory and biologics programs as well as the timing of internal and external product development projects, including increased clinical activities, payroll and material costs. These increases were partially offset by a decline in up front licensing and milestone payments, which totaled approximately \$18 million in 2014 compared to approximately \$49 million in the prior year.

Selling, General & Administrative Expense

Selling, general and administrative (“SG&A”) expense for the current year was \$1.63 billion, compared to \$1.41 billion for the prior year, an increase of \$217.2 million. SG&A increased due to increased selling and marketing costs of approximately \$52 million, primarily related to the EpiPen® Auto-Injector, which includes our direct-to-consumer marketing campaign. Additionally, as we continue to build our infrastructure in certain areas, we experienced increased employee costs of approximately \$60 million and software implementation costs of approximately \$13 million. To support anticipated new product launches within the North America region of the Generics segment, legal costs increased approximately \$11 million during 2014. In addition the Company incurred a current year loss on the disposal of certain assets of approximately \$16 million and increased costs related to acquisitions of approximately \$31 million.

Litigation Settlements, Net

During 2014, the Company recorded a \$47.9 million net charge for litigation settlements, compared to a net gain of \$14.6 million in the prior year. The charge in the current year was primarily related to the settlement of a European Commission matter of \$21.7 million, the settlement of an intellectual property matter and, to a lesser extent, litigation settlements related to product liability claims. In the prior year, the Company recognized a gain related to the settlement of patent-infringement matters totaling approximately \$25 million, including recoveries related to product launches. These recoveries were offset by a \$10.3 million charge related to the settlement of a European Commission matter.

Other Operating (Income) Expense, Net

During 2014, the Company recognized a gain of \$80.0 million as a result of an agreement with Strides Arcolab to settle a component of the contingent consideration related to the Agila acquisition. The gain recognized relates to the recovery of lost revenues in 2014 arising from supply disruptions that resulted from on-going quality-enhancement activities initiated at certain Agila facilities prior to the Company’s acquisition of Agila in 2013. In the prior year period, the Company recognized a charge of \$3.1 million related to fair value adjustments to contingent consideration.

Interest Expense

Interest expense for 2014 totaled \$333.2 million, compared to \$313.3 million for 2013. The increase in the current year is principally due to higher average debt balances, higher interest expense related to clean energy investments and non-cash accretion of contingent consideration liabilities. Included in interest expense is non-cash interest, primarily made up of the amortization of the discounts and premiums on our convertible debt instruments and senior notes totaling \$30.2 million for the current period and \$28.2 million for the prior year. Also included in interest expense is accretion of our contingent consideration liability related to certain acquisitions, which was \$35.3 million in the current year compared to \$32.3 million in the prior year.

Other Expense (Income), Net

Other expense (income), net, was expense of \$44.9 million in the current year, compared to expense of \$74.9 million in the prior year. Other expense (income), net includes losses from equity affiliates, foreign exchange gains and losses and interest and dividend income. In the current year, other expense (income), net included losses from equity affiliates of approximately \$91 million, principally related to the Company’s clean energy investments, charges of approximately \$33 million related to the redemption of the 6.000% Senior Notes due 2018 and the termination of forward starting swaps, partially offset by foreign exchange gains of approximately \$78 million. In the prior year, the

Company incurred charges of approximately \$64 million related to the redemption of the 7.625% Senior Notes due in 2017, comprised of the redemption premium and the write-off of deferred financing fees, as well as charges of approximately \$9 million in conjunction with the June 2013 Credit Agreement refinancing transaction related to the write-off of deferred financing fees.

Income Tax Expense

We recorded income tax expense of \$41.4 million in 2014, compared to income tax expense of \$120.8 million in 2013, a decrease of \$79.4 million. This decrease was primarily due to the Company receiving approvals in 2014 from the relevant Indian regulatory authorities to legally merge its wholly owned subsidiaries, Agila Specialties Private Limited and Onco Therapies Limited, into Mylan Laboratories Limited. The merger resulted in the recognition of a deferred tax asset of approximately \$150 million for the tax deductible goodwill in excess of the book goodwill with a corresponding benefit to income tax expense. In addition, during 2014, the Company recorded an increase in tax credits as a result of additional investments in facilities whose production is eligible for tax credits under Section 45 of the Internal Revenue Code of 1986, as amended of (the "Code"). Partially offsetting these items were increases in valuation allowances for net operating losses in foreign jurisdictions, lower net foreign tax credit benefits and additional amounts of uncertain tax positions in 2014.

2013 Compared to 2012

Total Revenues and Gross Profit

For the year ended December 31, 2013, Mylan reported total revenues of \$6.91 billion compared to \$6.80 billion in 2012. Total revenues include both net sales and other revenues from third parties. Third party net sales for 2013 were \$6.86 billion compared to \$6.75 billion for 2012, representing an increase of \$106.4 million, or 1.6%. Other third party revenues for 2013 were \$52.5 million compared to \$45.9 million in 2012, an increase of \$6.6 million.

Mylan's 2013 revenues were unfavorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in India, Australia and Japan. The unfavorable impact of foreign currency translation on 2013 total revenues was approximately \$123 million, or 2%. As such, constant currency total revenues increased approximately \$236 million, or 3%. The contribution from new product launches in 2013 of approximately \$285 million was not as significant as the contribution in 2012 of approximately \$922 million, a decline of approximately 69%. The North America region of the Generics segment accounted for the majority of this decline in the contribution from new product net sales in 2013 versus 2012. Offsetting the decline in new product net sales was 14% constant currency revenue growth in Rest of World region of the Generics segment and 18% constant currency revenue growth in the Specialty segment. Constant currency net sales from existing products decreased approximately \$56 million. The decrease was driven by a pricing decline of approximately \$377 million due to lower pricing within both Generics, partially offset by favorable pricing within Specialty. The pricing decline was partially offset by incremental volume within both Generics and Specialty, which contributed approximately \$321 million to 2013 sales. The operating results of Agila were included in Mylan's consolidated financial statements since the acquisition date, December 4, 2013, and were not material.

In arriving at net sales, gross revenues are reduced by provisions for estimates, including discounts, rebates, promotions, price adjustments, returns and chargebacks. See the section titled Application of Critical Accounting Policies in this Item 7, for a discussion of our methodology with respect to such provisions. For 2013, the most significant amounts charged against gross revenues were \$2.35 billion related to chargebacks and \$1.64 billion related to incentives offered to our direct customers, such as promotions and volume related incentives. For 2012, the most significant amounts charged against gross revenues were for chargebacks in the amount of \$2.35 billion and incentives offered to our direct customers in the amount of \$1.67 billion.

Cost of sales for 2013 was \$3.87 billion, compared to \$3.89 billion in 2012. Cost of sales in 2013 was impacted by the amortization of acquired intangible assets, and restructuring and other special items as described further in the section titled "Use of Non-GAAP Financial Measures." These items totaled approximately \$423.8 million in 2013. Cost of sales for 2012 included similar purchase accounting and restructuring and other special items in the amount of \$456.8 million. The decrease in 2013 of purchase accounting and restructuring and other special items was principally the result of a \$41.6 million in-process research and development ("IPR&D") impairment charge in 2012 as compared to an

impairment charge of \$18.0 million in 2013. Excluding these amounts, Adjusted Cost of Sales increased in 2013 to \$3.45 billion from \$3.43 billion, corresponding to the increase in sales.

Gross profit for 2013 was \$3.04 billion and gross margins were 44.0%. For 2012, gross profit was \$2.91 billion, and gross margins were 42.8%. Excluding the purchase accounting, restructuring and other special items discussed in the paragraph above, Adjusted Gross Margins were approximately 50% in both 2013 and 2012. Gross margins were favorably impacted in 2013 as a result of new product introductions by approximately 130 basis points and favorable pricing and volume on EpiPen® Auto-Injector in our Specialty segment by approximately 70 basis points. These increases were almost entirely offset by lower pricing on existing products within the Generics segment.

From time to time, a limited number of our products may represent a significant portion of our net sales, gross profit and net earnings. Generally, this is due to the timing of new product launches and the amount, if any, of additional competition in the market. Our top ten products in terms of sales, in the aggregate, represented approximately 31% and 28% of total revenues in 2013 and 2012, respectively.

Generics Segment

For 2013, Generics third party net sales were \$5.87 billion compared to \$5.91 billion in 2012, a decrease of \$40.0 million, or 0.7%. Generics constant currency third party net sales for 2013 increased by approximately \$83 million, or 1%.

Third party net sales from North America were \$3.01 billion for 2013, compared to \$3.23 billion for 2012, representing a decrease of \$218.8 million, or 6.8%. The decrease in 2013 third party net sales was due to a greater amount of net sales from new product launches in 2012 versus 2013. Third party net sales from new product launches totaled approximately \$198 million in 2013, compared to \$784 million in 2012, a decrease of approximately 75%. The effect of foreign currency translation was insignificant within North America.

Products generally contribute most significantly to revenues and gross margins at the time of their launch, even more so in periods of market exclusivity, or in periods of limited generic competition. As such, the timing of new product introductions can have a significant impact on Mylan's financial results. The entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. Additionally, pricing is often affected by factors outside of the Company's control.

Third party net sales from Europe were \$1.43 billion in 2013, compared to \$1.30 billion in 2012, an increase of \$132.1 million, or 10.2%. Constant currency third party net sales from Europe in 2013 resulted in a year-over-year increase of approximately \$98 million, or 8%. This increase was the result of a double-digit increase in constant currency third party net sales in France and Italy as a result of net sales from new products and favorable volumes. Partially offsetting this increase was lower pricing in a number of European markets in which Mylan operates, as a result of government imposed pricing reductions and competitive market conditions.

Local currency third party net sales from Mylan's businesses in France and Italy increased in 2013 as compared to 2012 as a result of new product launches and higher volumes on existing products partially offset by the impact of lower pricing due to government-imposed pricing reductions and an increasingly competitive market. Our market share in France remained relatively stable in 2013 as compared to 2012, and we remain the market leader.

In the U.K., local currency third party net sales increased by double digits in 2013 versus 2012 as a result of favorable pricing on existing products combined with new product introductions.

In addition to France and Italy, certain other markets in which we do business, including Spain, have undergone government-imposed price reductions, and further government-imposed price reductions are expected in the future. Such measures, along with the tender systems discussed below, are likely to have a negative impact on net sales and gross profit in these markets. However, government initiatives in certain markets that appear to favor generic products could help to mitigate this unfavorable effect by potentially increasing rates of generic substitution and penetration.

A number of markets in which we operate have implemented tender systems for generic pharmaceuticals in an effort to lower prices. Generally speaking, tender systems can have an unfavorable impact on revenue and profitability. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the

tender. Additionally, the loss of a tender by a third party to whom we supply API can also have a negative impact on our sales and profitability. Sales, primarily in Germany, continue to be negatively affected by the impact of tender systems.

In Rest of World, third party net sales were \$1.44 billion in 2013, compared to \$1.39 billion in 2012, an increase of \$46.7 million, or 3.4%. Rest of World constant currency third party net sales would have increased by approximately \$200 million, or 14%. This increase was primarily driven by higher third party net sales by our operations in India, particularly in the ARV franchise, as well as double digit constant currency growth in Japan.

The increase in third party net sales from our operations in India was due to significant growth in sales of ARV products used in the treatment of HIV/AIDS, both as FDF generic products and API. In addition to third party net sales, Rest of

World region also supplied both FDF generic products and API to Mylan subsidiaries in conjunction with Mylan's vertical integration strategy. Intercompany sales recognized by Rest of World region were \$678.3 million in 2013, compared to \$595.6 million in 2012. These intercompany sales eliminate within, and therefore are not included in, Generics or consolidated net sales.

In Japan, third party net sales increased by double digits as a result of higher volumes and new product introductions. In Australia, local currency third party net sales were slightly lower in 2013 than 2012 as a result of significant government-imposed pricing reform, partially offset by new product sales and incremental volumes on existing products. As in Europe, both Australia and Japan have undergone government-imposed price reductions which have had a negative impact on sales and gross profit in these markets.

Specialty Segment

For 2013, Specialty reported third party net sales of \$981.7 million, an increase of \$146.3 million, or 17.6%, from third party net sales in 2012 of \$835.4 million. The increase was principally the result of higher sales of the EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions (anaphylaxis), as a result of favorable pricing and increased volumes. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The market continues to grow as awareness of the risk of anaphylaxis increases. In addition, sales of the Perforomist® Inhalation Solution increased by double digits from 2012 as a result of favorable pricing.

Operating Expenses

Research & Development Expense

R&D expense in 2013 was \$507.8 million, compared to \$401.3 million in 2012, an increase of \$106.5 million. R&D increased in 2013 primarily due to the expenses related to the development of our respiratory and biologics programs as well as the timing of internal and external product development projects. In addition, during 2013 the Company incurred up front licensing and milestone payments of approximately \$49.4 million.

Selling, General & Administrative Expense

SG&A expense for 2013 was \$1.41 billion, compared to \$1.39 billion for 2012, an increase of \$16.1 million. Primary factors contributing to the increase in SG&A include an increase in certain payroll and related employee benefit costs of approximately \$42 million as we continue to build out our infrastructure in certain areas and costs related to acquisitions of approximately \$37 million. These items were partially offset by lower sales and marketing costs in Japan of approximately \$29 million, as a result of the collaboration with Pfizer Japan Inc. ("Pfizer Japan") and lower marketing and advertising related costs within our Specialty segment of approximately \$14 million.

Litigation Settlements, Net

During 2013, the Company recorded a \$14.6 million net gain for litigation settlements, compared to a net gain of \$3.1 million during 2012. The net gain in litigation settlements in 2013 was principally related to recoveries of lost profits in patent-infringement matters totaling approximately \$25 million, including recoveries related to product launches. These recoveries were partially offset by a \$10.3 million charge related to a European Commission matter. In 2012, the Company recorded a \$3.1 million net gain comprised of gains of approximately \$34 million for the favorable resolution of patent infringement matters, partially offset by an approximate \$20 million charge related to pricing litigation matters and other patent infringement matters.

Other Operating (Income) Expense, Net

In 2013, the Company recognized a charge of \$3.1 million related to fair value adjustments to contingent consideration. In 2012, the Company recognized a charge of \$8.3 million related to fair value adjustments to contingent consideration.

Interest Expense

Interest expense for 2013 totaled \$313.3 million, compared to \$308.7 million for 2012. The increase in 2013 was primarily due to higher interest expense related to clean energy investments and non-cash accretion of contingent

consideration liabilities. Included in interest expense is the amortization of discounts and premiums on our convertible debt instruments and

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senior notes, which totaled \$28.2 million in 2013 and \$29.4 million in 2012. Also included in interest expense for 2013 was \$32.3 million of accretion of our contingent consideration liability compared to \$30.7 million in 2012.

Other Expense (Income), Net

Other expense (income), net, was expense of \$74.9 million in 2013 compared to income of \$3.5 million in 2012. Other expense (income), net in 2013 included charges of approximately \$63.9 million related to the redemption of the 7.625% Senior Notes due 2017, comprised of the redemption premium and the write-off of deferred financing fees. In addition, the Company incurred charges of approximately \$8.7 million related to the write-off of deferred financing fees in conjunction with the refinancing of the senior credit facility. Also included are losses from equity affiliates, foreign exchange transaction gains and losses and interest and dividend income.

Income Tax Expense

We recorded income tax expense of \$120.8 million in 2013 compared to income tax expense of \$161.2 million in 2012, a decrease of \$40.4 million. This decrease was primarily due to a lower pre-tax income; an increase in business tax credits as a result of additional investments made during the year in facilities whose production is eligible for credits under Section 45 of the Code; a reduction in income subject to tax in the U.S.; and the retroactive effect of federal tax legislation enacted in January 2013. Partially offsetting these items were increases in valuation allowances for net operating losses in foreign jurisdictions, lower net foreign tax credit benefits and lower releases and settlements of uncertain tax positions in 2013. Also affecting the Company's changes to its tax provision were higher levels of income earned in jurisdictions with tax rates below the U.S. rate.

Use of Non-GAAP Financial Measures

Whenever the Company uses non-GAAP financial measures, it will provide a reconciliation of the non-GAAP financial measures to their most directly comparable U.S. GAAP financial measure. Investors and other readers are encouraged to review the related U.S. GAAP financial measures and the reconciliation of non-GAAP measures to their most directly comparable U.S. GAAP measure set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with U.S. GAAP. Additionally, since these are not measures determined in accordance with U.S. GAAP, they have no standardized meaning prescribed by U.S. GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies.

Adjusted Cost of Sales and Adjusted Gross Margin

We use the non-GAAP financial measure "Adjusted Cost of Sales" and the corresponding "Adjusted Gross Margin." We believe that these non-GAAP financial measures are useful supplemental information for our investors and when considered together with our U.S. GAAP financial measures and the reconciliation to the most directly comparable U.S. GAAP financial measure, provide a more complete understanding of the factors and trends affecting our operations. The principal items excluded from Adjusted Cost of Sales include acquisition related items and restructuring and other special items, both of which are described in greater detail below.

A reconciliation between cost of sales, as reported under U.S. GAAP, and Adjusted Cost of Sales and Adjusted Gross Margin for the periods shown follows:

	Year Ended December 31,			
	2014	2013	2012	
GAAP cost of sales	\$4,191.6	\$3,868.8	\$3,887.8	
Deduct:				
Purchase accounting related amortization	(403.6)	(369.1)	(391.1)	
Restructuring & other special items	(113.7)	(54.7)	(65.7)	
Adjusted cost of sales	\$3,674.3	\$3,445.0	\$3,431.0	
Adjusted gross profit ^(a)	\$4,045.3	\$3,464.1	\$3,365.1	
Adjusted gross margin ^(a)	52	% 50	% 50	%

^(a) Adjusted Gross Profit is calculated as total revenues less Adjusted Cost of Sales. Adjusted Gross Margin is calculated as Adjusted Gross Profit divided by total revenue.

Adjusted Earnings and Adjusted EPS

Adjusted Earnings is a non-GAAP financial measure and provides an alternative view of performance used by management. Management believes that, primarily due to acquisitions, an evaluation of the Company's ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with U.S. GAAP. Adjusted Earnings and Adjusted Earnings per Diluted Share ("Adjusted EPS") are two of the most important internal financial metrics related to the ongoing operating performance of the Company, and management also believes that investors' understanding of our performance is enhanced by these adjusted measures. Actual internal and forecasted operating results and annual budgets include Adjusted Earnings and Adjusted EPS, and the financial performance of the Company is measured by senior management on this basis along with other performance metrics. Management's annual incentive compensation is derived in part based on the Adjusted EPS metric.

The significant items excluded from Adjusted Cost of Sales, Adjusted Earnings and Adjusted EPS include:

Acquisition-Related Items

The ongoing impact of certain amounts recorded in connection with acquisitions is excluded from Adjusted Cost of Sales, Adjusted Earnings and Adjusted EPS. These amounts include the amortization of intangible assets and inventory step-up, intangible asset impairment charges (including IPR&D), accretion and the fair value adjustments related to contingent consideration and certain acquisition financing related costs. These costs are excluded because management believes that excluding them is helpful to understanding the underlying, ongoing operational performance of the business.

Restructuring and Other Special Items

Costs related to restructuring and other actions are excluded from Adjusted Cost of Sales, Adjusted Earnings and Adjusted EPS, as applicable. These amounts include items such as:

- Exit costs associated with facilities to be closed or divested, including employee separation costs, impairment charges, accelerated depreciation, incremental manufacturing variances, equipment relocation costs and other exit costs;

- Certain acquisition related integration costs, as well as other costs associated with acquisitions and other business transformation and/or optimization initiatives, which are not part of a formal restructuring program, including employee separation and post-employment costs;

Certain transition and other costs associated with the ratification of a new collective bargaining agreement in 2012 governing certain employees at our Morgantown, West Virginia manufacturing facility, including the withdrawal obligation from a multi-employer pension plan;

The pre-tax loss of the Company's investments in clean energy investments, whose activities qualify for income tax credits under Section 45 of the Code; only included in Adjusted Earnings and Adjusted EPS is the net tax effect of the entity's activities;

Certain costs to further develop and optimize our global enterprise resource planning systems, operations and supply chain; and

Certain costs related to new operations and significant alliances/business partnerships, including certain upfront and/or milestone research and development related payments.

The Company has undertaken restructurings and other optimization initiatives of differing types, scope and amount during the covered periods and, therefore, these charges should not be considered non-recurring; however, management excludes these amounts from Adjusted Earnings and Adjusted EPS because it believes it is helpful to understanding the underlying, ongoing operational performance of the business.

Litigation Settlements, net

Charges and gains related to legal matters, such as those discussed in the Notes to Consolidated Financial Statements — Note 14, "Contingencies" are generally excluded from Adjusted Earnings and Adjusted EPS. Normal, ongoing defense costs of the Company made in the normal course of our business are not excluded.

Reconciliation of Adjusted Earnings and Adjusted EPS

A reconciliation between net earnings attributable to Mylan Inc. common shareholders and diluted earnings per share attributable to Mylan Inc. common shareholders, as reported under U.S. GAAP, and Adjusted Earnings and Adjusted EPS for the periods shown follows:

(In millions, except per share amounts)	Year Ended December 31,					
	2014		2013		2012	
GAAP net earnings attributable to Mylan Inc. and GAAP diluted EPS	\$929.4	\$2.34	\$623.7	\$1.58	\$640.9	\$1.52
Purchase accounting related amortization (primarily included in cost of sales) ^(a)	419.0		371.1		391.1	
Litigation settlements, net	47.9		(9.9)		(3.0)	
Interest expense, primarily amortization of convertible debt discount	46.0		38.0		35.6	
Non-cash accretion and fair value adjustments of contingent consideration liability	35.3		35.4		38.7	
Clean energy investment subsidiary pre-tax loss ^(b)	78.9		22.4		16.8	
Financing related costs (included in other income, net)	33.3		72.6		—	
Acquisition related costs (primarily included in cost of sales and selling, general and administrative expense)	139.5		49.8		—	
Restructuring and other special items included in:						
Cost of sales	45.1		49.3		65.7	
Research and development expense	17.9		51.6		12.4	
Selling, general and administrative expense	66.9		70.6		104.9	
Other income (expense), net	(10.9)		25.2		(0.7)	
Tax effect of the above items and other income tax related items ^(c)	(432.0)		(259.9)		(215.7)	
Adjusted net earnings attributable to Mylan Inc. and adjusted diluted EPS	\$1,416.3	\$3.56	\$1,139.9	\$2.89	\$1,086.7	\$2.59
Weighted average diluted common shares outstanding	398.0		394.5		420.2	

^(a) Purchase accounting related amortization expense for the years ended December 31, 2014, 2013 and 2012 includes intangible asset impairment charges of \$27.7 million, \$18.0 million and \$41.6 million, respectively.

^(b) Adjustment represents exclusion of the pre-tax loss related to Mylan's clean energy investments, the activities of which qualify for income tax credits under Section 45 of the Code. Amount is included in other expense (income), net.

^(c) Adjustment for other income tax related items includes the exclusion from Adjusted Net Earnings of the tax benefit of approximately \$150 million related to the merger of the Company's wholly owned subsidiaries, Agila Specialties Private Limited and Onco Therapies Limited, into Mylan Laboratories Limited for the year ended December 31, 2014.

Liquidity and Capital Resources

Our primary source of liquidity is cash provided by operations, which was \$1.01 billion for the year ended December 31, 2014. We believe that cash provided by operating activities and available liquidity will continue to allow us to meet our needs for working capital, capital expenditures, interest and principal payments on debt obligations and other cash needs over the next several years. Nevertheless, our ability to satisfy our working capital requirements and debt service obligations, or fund planned capital expenditures, will substantially depend upon our future operating performance (which will be affected by prevailing economic conditions), and financial, business and

other factors, some of which are beyond our control.

Net cash provided by operating activities decreased by \$91.8 million to \$1.01 billion for the year ended December 31, 2014, as compared to \$1.11 billion for the year ended December 31, 2013. The net decrease in cash provided by operating activities was principally due to the following:

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an increase in the amount of cash used for other operating assets and liabilities, net of \$259.1 million, principally due to an increase in cash paid for accrued litigation settlements of \$66.6 million as well as an increase in cash paid related to the settlement of derivative and foreign exchange contracts;

a net decrease in the amount of cash provided by changes in trade accounts payable of \$137.5 million as a result of the timing of cash disbursements;

a net increase in the amount of cash used for accounts receivable, including estimated sales allowances, of \$23.5 million reflecting the timing of sales, cash collections and disbursements related to sales allowances; and

a net increase in the amount of cash used through changes in deferred income taxes of \$228.1 million.

These items were offset by the following:

an increase in net earnings of \$306.6 million, which includes a net increase of \$160.4 million in the amount of non-cash expenses, principally as a result of increased depreciation and amortization as a result of prior year acquisitions, increased losses from equity method investments and a number of other non-cash charges including stock compensation, restructuring charges and the accretion of the contingent consideration liabilities; and

a net increase in the amount of cash provided by changes in income taxes of \$79.6 million as a result of the level of estimated tax payments made during the current year.

Net cash provided by operating activities increased by \$157.6 million to \$1.11 billion for the year ended December 31, 2013 as compared to \$949.0 million for the year ended December 31, 2012. The net increase in cash provided by operating activities was principally due to the following:

a net increase in cash provided through changes in legal and professional accruals of \$135.0 million, primarily as a result of a higher amount of litigation payments in 2012;

a net increase in cash of \$25.0 million for cash collected from litigation settlements;

a net decrease in the amount of cash used through changes in income taxes of \$48.9 million as a result of the level of estimated tax payments made in 2013;

a net increase in the amount of cash provided by changes in trade accounts payable of \$55.8 million as a result of the timing of cash disbursements; and

a net decrease of \$14.9 million in the amount of cash used through changes in inventory balances. The decrease in cash utilized for inventory in 2013 (as compared to 2012) reflects a lower level of increases in raw material, work in process and finished goods inventories as compared to the prior year. The higher prior year investment was primarily due to an inventory build in late 2012 in anticipation of additional manufacturing capacity in India that came on-line in early 2013. Nevertheless, we continued to invest in inventory in 2013 primarily to support anticipated volume growth as a result of projected increases in generic utilization, particularly in certain European markets.

These items were partially offset by the following:

a decrease in net earnings of \$16.5 million, combined with a net decrease in the amount of non-cash expenses for depreciation and amortization totaling \$30.6 million as a result of higher 2012 IPR&D impairment charges;

a net increase in the amount of cash used for accounts receivable, including estimated sales allowances, of \$118.4 million reflecting the timing of sales, cash collections and disbursements related to sales allowances; and

during 2013, the Company redeemed its 7.625% Senior Notes due 2017 for a total of \$608.8 million, including a \$58.8 million redemption premium that is included as an outflow in cash from operating activities.

Cash used in investing activities was \$800.3 million for the year ended December 31, 2014, as compared to cash used in investing activities of \$1.87 billion for the year ended December 31, 2013, a decrease of \$1.07 billion. The decrease in cash used in investing activities was principally the result of cash paid for acquisitions in 2013 totaling \$1.3 billion primarily related to the Agila acquisition, as compared to \$50.0 million in the current year. In 2014, payments for product rights and other investing activities, net, totaled \$429.1 million for the year ended December 31, 2014, as compared to \$60.9 million in the prior year period. The increase was the result of the acquisition of certain commercialization rights in the U.S. and other countries in the current year. Cash paid for acquisitions was \$50.0 million in 2014. Capital expenditures, primarily for equipment and facilities, were approximately \$325.3 million in the current year, as compared to \$334.6 million in the comparable prior year. The decrease as compared to 2013 is the result of the timing of expenditures. While there can be no assurance that current expectations will be realized, we expect to continue to invest in our future growth and expect capital expenditures for 2015 to be between \$400 million and \$500 million. In addition, during 2013, restricted cash increased \$228.0 million, principally related to amounts deposited in escrow, or other restricted accounts, for potential contingent consideration payments related to the Agila acquisition.

Cash used in financing activities was \$267.4 million for the year ended December 31, 2014, as compared to cash provided by financing activities of \$692.9 million for the year ended December 31, 2013, a net change of \$960.3 million. During 2014, the Company entered into a New Senior Term Credit Agreement with a syndicate of banks which provided an \$800 million 2014 Term Loan. The proceeds of the 2014 Term Loan were used for working capital expenditures and to repay outstanding borrowings under the Company's June 2013 Credit Agreement. Borrowings under the June 2013 Credit Agreement were used to fund the redemption of the November 2018 Senior Notes. During 2014, net repayments under our Revolving Facility totaled \$60 million. The Company repaid approximately \$107.8 million of short-term borrowings under our Receivables Facility and the working capital facilities in India. The Company also paid \$150.0 million of contingent consideration to Strides Arcolab related to the Agila acquisition during the third quarter of 2014.

During 2014, the Company did not repurchase any shares of common stock. During 2013, the Company repurchased approximately 28.5 million shares of common stock for aggregate consideration of approximately \$1.0 billion.

The Company's next significant debt maturity is in the third quarter of 2015, and our current intention is to refinance either through future debt offerings or borrowings under the New Revolving Facility. In addition, our cash and cash equivalents at our foreign operations totaled \$110 million at December 31, 2014. The majority of these funds represented earnings considered to be permanently reinvested to support the growth strategies of our foreign subsidiaries. The Company anticipates having sufficient U.S. liquidity, including existing borrowing capacity and cash to be generated from operations, to fund foreseeable U.S. cash needs without requiring the repatriation of foreign cash. If these funds are needed for the Company's operations in the U.S., the Company may be required to accrue and pay U.S. taxes to repatriate these funds.

As of December 31, 2014, because the closing price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day in the December 31, 2014 period was more than 130% of the applicable conversion reference price of \$13.32 at December 31, 2014, the \$573.1 million of Cash Convertible Notes were currently convertible. Although de minimis conversions have been requested, the Company's experience is that convertible debentures are not normally converted by investors until close to their maturity date. Upon an investor's election to convert, the Company is required to pay the full conversion value in cash. Should holders elect to convert, the Company intends to draw on its New Revolving Facility to fund any principal payments. The amount payable per \$1,000 notional bond would be calculated as the product of (1) the conversion reference rate (currently 75.0751) and (2) the average Daily Volume Weighted Average Price per share of common stock for a specified period following the conversion date. Any payment above the principal amount is matched by a convertible note hedge.

In connection with the consummation of the Transaction, we and New Mylan executed a supplemental indenture that amended the indenture governing the Cash Convertible Notes so that, among other things, all relevant determinations for purposes of the cash conversion rights to which holders may be entitled from time-to-time in accordance with such indenture shall be made by reference to the New Mylan ordinary shares.

We are involved in various legal proceedings that are considered normal to our business. While it is not possible to predict the outcome of such proceedings, an adverse outcome in any of these proceedings could materially affect our financial position and results of operations, including our operating cash flow and could cause the market value of our stock to decline. We have approximately \$40 million accrued for such legal contingencies. For certain contingencies assumed in conjunction with the acquisition of the former Merck Generics business, Merck KGaA, the seller, has indemnified Mylan. We have also been indemnified for certain contingencies by Strides Arcolab related to our acquisition of Agila. The inability or denial of

Merck KGaA, Strides Arcolab or another indemnitor or insurer to pay on an indemnified claim could have a material adverse effect on our financial position, results of operations or cash flows, and could cause the market value of our stock to decline.

We are actively pursuing, and are currently involved in, joint projects related to the development, distribution and marketing of both generic and branded products. Many of these arrangements provide for payments by us upon the attainment of specified milestones. While these arrangements help to reduce the financial risk for unsuccessful projects, fulfillment of specified milestones or the occurrence of other obligations may result in fluctuations in cash flows.

We are continuously evaluating the potential acquisition of products, as well as companies, as a strategic part of our future growth. Consequently, we may utilize current cash reserves or incur additional indebtedness to finance any such acquisitions, which could impact future liquidity. In addition, on an ongoing basis, we review our operations including the evaluation of potential divestitures of products and businesses as part of our future strategy. Any divestitures could impact future liquidity.

At December 31, 2014 and 2013, we had \$43.7 million and \$53.2 million outstanding under existing letters of credit, respectively. Additionally, as of December 31, 2014, we had \$144.9 million available under the \$150.0 million subfacility on our New Revolving Facility for the issuance of letters of credit.

Mandatory minimum repayments remaining on the outstanding long term debt at December 31, 2014, excluding the discounts, premium and conversion features, are as follows for each of the periods ending December 31:

(In millions)	Total
2015	\$573
2016	1,000
2017	800
2018	650
2019	500
Thereafter	2,750
Total	\$6,273

In December 2014, the Company entered into the \$1.5 billion New Revolving Facility, which expires in December 19, 2019. The New Revolving Facility includes a \$150 million subfacility for the issuance of letters of credit and a \$125 million subfacility for swingline borrowings. The interest rate on borrowings under the New Revolving Facility at December 31, 2014 was LIBOR plus 1.325% per annum. The New Revolving Facility has a facility fee which is 0.175%. At December 31, 2014, the Company had no amounts outstanding under the New Revolving Facility. In December 2014, in connection with its entry into the New Revolving Facility, the Company terminated the June 2013 Credit Agreement.

The new Senior Credit Agreement contains customary affirmative covenants for facilities of this type, including among others, covenants pertaining to the delivery of financial statements, notices of default and certain material events, maintenance of corporate existence and rights, business, property, and insurance and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of subsidiary indebtedness, liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, payments of dividends and other restricted payments and changes in our lines of business. The new Senior Credit Agreement also contains a maximum consolidated leverage ratio financial covenant. We have been compliant with the financial covenant during 2014, and we expect to remain in compliance for the next twelve months.

Under the terms of the Receivables Facility, our subsidiary, Mylan Pharmaceuticals Inc. (“MPI”), sells certain accounts receivable to Mylan Securitization a wholly owned special purpose entity which in turn sells a percentage ownership interest in the receivables to financial institutions and commercial paper conduits sponsored by financial institutions. MPI is the servicer of the receivables under the Receivables Facility. Purchases under the Receivables Facility will be repaid as accounts receivable are collected, with new purchases being advanced as new accounts receivable are originated by MPI.

Under the Company’s Receivables Facility, any amounts outstanding under the facility are recorded as a secured loan and included in short-term borrowings, and the receivables underlying any borrowings are included in accounts receivable, net, in the Consolidated Balance Sheets. In January 2015, the Receivables Facility was amended and restated, and its maturity was extended through January 2018. At December 31, 2014, there were \$325 million of short-term borrowings outstanding under

the Receivables Facility. The size of the Receivables Facility may be increased from time to time, upon request by Mylan Securitization and with the consent of the purchaser agents and the Agent, up to \$500 million.

Short-term borrowings held by the Company's subsidiaries in India at December 31, 2014 totaled approximately \$6 million and had a weighted average interest rate of 10.9%. The borrowings represent working capital facilities and are secured by Mylan India's current assets.

The fair value measurement of contingent consideration is determined using unobservable inputs based on the Company's own assumptions. Significant unobservable inputs in the valuation include the probability and timing of future development and commercial milestones and future profit sharing payments. A discounted cash flow method was used to value contingent consideration at December 31, 2014 and 2013, which was calculated as the present value of the estimated future net cash flows using a market rate of return at December 31, 2014 and 2013. Discount rates ranging from 0.8% to 11.3% were utilized in the valuation. Significant changes in unobservable inputs could result in material changes to the contingent consideration liability.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2014 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

(In millions)	Total	Less than One Year	One- Three Years	Three- Five Years	Thereafter
Operating leases	\$179.7	\$37.3	\$58.3	\$21.8	\$62.3
Long-term debt	6,273.3	573.3	1,800.0	1,150.0	2,750.0
Scheduled interest payments	1,858.7	232.0	400.8	333.1	892.8
Other Commitments ⁽¹⁾	2,100.6	688.1	561.9	524.5	326.1
	\$10,412.3	\$1,530.7	\$2,821.0	\$2,029.4	\$4,031.2

Other commitments include the estimated liability payment related to the withdrawal from a multi-employer ⁽¹⁾ pension plan, funding commitments related to the Company's clean energy investments, agreements to purchase third-party manufactured products and open purchase orders at December 31, 2014.

We lease certain property under various operating lease arrangements that expire generally over the next five years. These leases generally provide us with the option to renew the lease at the end of the lease term.

At December 31, 2014, the \$2.41 billion of debt related to the Cash Convertible Notes reported in our financial statements consists of \$525 million of debt (\$573 million face amount, net of \$21 million discount) and a liability with a fair value of \$1.85 billion related to the bifurcated conversion feature. The bifurcated conversion feature is not included in contractual obligations as there is an offsetting hedge asset.

Scheduled interest payments represent the estimated interest payments related to our outstanding borrowings under term loans, notes and other debt. Variable debt interest payments are estimated using current interest rates.

Due to the uncertainty with respect to the timing of future payments, if any, the following contingent payments have not been included in the table above.

In conjunction with the acquisition of Agila on December 4, 2013, the Company recorded estimated contingent consideration totaling \$250 million as part of the purchase price. During the third quarter of 2014, the Company entered into an agreement with Strides Arcolab to settle a portion of the contingent consideration for \$150 million, for which the Company accrued \$230 million at the acquisition date. As a result of this agreement, the Company recognized a gain of \$80 million during the year ended December 31, 2014, which is included in other operating

(income) expense, net in the Consolidated Statements of Operations. The remaining contingent consideration, which could total a maximum of \$211 million, is primarily related to the satisfaction of certain regulatory conditions, including potential regulatory remediation costs and the resolution of certain pre-acquisition contingencies.

We are contractually obligated to make potential future development, regulatory and commercial milestone, royalty and/or profit sharing payments in conjunction with collaborative agreements or acquisitions we have entered into with third parties. The most significant of these relates to the potential future consideration related to the respiratory delivery platform. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. The amount of the contingent consideration liability was \$470 million at December 31, 2014. In addition, the Company expects to incur approximately \$35 million to \$40 million of annual non-cash accretion expense related to the increase in the net present value of the contingent consideration liability.

On January 30, 2015, the Company entered into a development and commercialization collaboration with Theravance Biopharma for the development and, subject to FDA approval, commercialization of a novel once-daily nebulized LAMA for COPD and other respiratory diseases. Under the terms of the agreement, Mylan and Theravance Biopharm will co-develop the product. In the U.S., Mylan will lead commercialization and Theravance Biopharma will retain the right to co-promote the product under a profit-sharing arrangement. In addition to funding the U.S. registrational development program, Mylan will pay Theravance Biopharma an initial payment of \$15 million in the second quarter of 2015 and made a \$30 million equity investment in Theravance Biopharma. Under the terms of the agreement, Theravance Biopharma is eligible to receive potential development and sales milestone payments totaling \$220 million in the aggregate.

In the fourth quarter of 2013, the Company entered into a licensing agreement with Pfizer for the exclusive worldwide rights to develop, manufacture and commercialize a novel long-acting muscarinic antagonist compound. As part of the agreement, the Company made an upfront development payment, which is included as a component of R&D expense in 2013, and could make additional payments upon the achievement of certain milestones as the Company's development continues over the next several years. Depending on the commercialization of this novel compound and the level of future sales and profits, the Company could also be obligated to make payments upon the occurrence of certain sales milestones, along with sales royalties and profit sharing payments.

We have entered into an exclusive collaboration on the development, manufacturing, supply and commercialization of multiple, high value generic biologic compounds and three insulin analog products for the global marketplace. We plan to provide funding related to the collaboration over the next several years that could total approximately \$75 million or more per year. Additionally, we have entered into product development agreements under which we have agreed to share in the development costs as they are incurred by our partners and/or pay milestones. As the timing of cash expenditures is dependent upon a number of factors, many of which are outside of our control, it is difficult to forecast the amount of payments to be made over the next few years, which could be significant.

We periodically enter into licensing agreements with other pharmaceutical companies for the manufacture, marketing and/or sale of pharmaceutical products. These agreements generally call for us to pay a percentage of amounts earned from the sale of the product as a royalty on a profit share.

With respect to the timing of future cash flows associated with our unrecognized tax benefits at December 31, 2014, we are unable to make reasonably reliable estimates of the period of cash settlement with the respective taxing authority. As such, \$191.2 million of unrecognized tax benefits have been excluded from the contractual obligations table above.

We sponsor various defined benefit pension plans in several countries. Benefit formulas are based on varying criteria on a plan by plan basis. We fund non-domestic pension liabilities in accordance with laws and regulations applicable to those plans, which typically results in these plans being unfunded. The amount accrued related to these benefits was \$68.7 million at December 31, 2014. We are unable to determine when these amounts will require payment as the timing of cash expenditures is dependent upon a number of factors, many of which are outside of our control.

We have entered into employment and other agreements with certain executives and other employees that provide for compensation and certain other benefits. These agreements provide for severance payments under certain circumstances. Certain commercial agreements require us to provide performance bonds and/or indemnification; while it is difficult to forecast the amount of payments, if any, to be made over the next few years, we do not believe the amount would be material to our results of operations, cash flows or financial condition.

Impact of Currency Fluctuations and Inflation

Because our results are reported in U.S. Dollars, changes in the rate of exchange between the U.S. Dollar and the local currencies in the markets in which we operate, mainly the Euro, Indian Rupee, Japanese Yen, Australian Dollar, Canadian

Dollar, Pound Sterling and Brazilian Real affect our results as previously noted. We do not believe that inflation has had a material impact on our revenues or operations.

Application of Critical Accounting Policies

Our significant accounting policies are described in Note 2 to Consolidated Financial Statements and are in accordance with U.S. GAAP.

Included within these policies are certain policies which contain critical accounting estimates and, therefore, have been deemed to be “critical accounting policies.” Critical accounting estimates are those which require management to make assumptions about matters that were uncertain at the time the estimate was made and for which the use of different estimates, which reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur from period to period could have a material impact on our financial condition or results of operations. We have identified the following to be our critical accounting policies: the determination of net revenue provisions, business acquisitions, intangible assets, goodwill and contingent consideration, income taxes and the impact of existing legal matters.

Net Revenue Provisions

Net revenues are recognized for product sales when title and risk of loss have transferred to the customer and when provisions for estimates, including discounts, sales allowances, price adjustments, returns, chargebacks and other promotional programs are reasonably determinable. Accruals for these provisions are presented in the Consolidated Financial Statements as reductions in determining net revenues and in accounts receivable and other current liabilities. Accounts receivable are presented net of allowances relating to these provisions, which were \$1.63 billion and \$1.24 billion at December 31, 2014 and 2013, respectively. Other current liabilities include \$581.3 million and \$281.1 million at December 31, 2014 and 2013, respectively, for certain sales allowances and other adjustments that are paid to indirect customers. The following is a rollforward of the most significant provisions for estimated sales allowances during 2014:

(In millions)	Balance at December 31, 2013	Checks/ Credits Issued to Third Parties	Current Provision Related to Sales Made in the Current Period	Effects of Foreign Exchange	Balance at December 31, 2014
Chargebacks	\$461.6	\$(3,473.2)	\$3,605.2	\$(2.1)	\$591.5
Incentives offered to direct customers	\$539.3	\$(1,549.5)	\$1,736.2	\$(19.6)	\$706.4
Returns	\$167.5	\$(152.5)	\$235.9	\$(2.7)	\$248.2

We have not made and do not anticipate making any significant changes to the methodologies that we use to measure chargebacks, incentives offered to direct customers or returns; however, the balances within these reserves can fluctuate significantly through the consistent application of our methodologies. In the current year, accruals for incentives offered to direct customers increased as a result of an increase in related sales and overall higher rebate rates, mainly in response to the competitive environment in various markets. Historically, we have not recorded in any current period any material amounts related to adjustments made to prior period reserves.

Provisions for estimated discounts, sales allowances, promotional and other credits require a lower degree of subjectivity and are less complex in nature, yet, when combined, represent a significant portion of the overall provisions. These provisions are estimated based on historical payment experience, historical relationships to

revenues, estimated customer inventory levels and contract terms. Such provisions are determinable due to the limited number of assumptions and consistency of historical experience. Others, such as chargebacks and returns, require management to make more subjective judgments and evaluate current market conditions. These provisions are discussed in further detail below.

Chargebacks — The provision for chargebacks is the most significant and complex estimate used in the recognition of revenue. Mylan markets products directly to wholesalers, distributors, retail pharmacy chains, mail order pharmacies and group purchasing organizations. We also market products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and pharmacy benefit management companies, collectively referred to as “indirect customers.” Mylan enters into agreements with its indirect customers to establish contract pricing for certain products. The indirect customers then independently select a wholesaler from which to actually purchase the products at these contracted prices. Alternatively, certain wholesalers may enter into agreements with indirect customers that establish contract pricing for certain products, which the

wholesalers provide. Under either arrangement, Mylan will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. Such credit is called a chargeback, while the difference between the contracted price and the wholesaler's invoice price is referred to as the chargeback rate. The provision for chargebacks is based on expected sell-through levels by our wholesaler customers to indirect customers, as well as estimated wholesaler inventory levels. For the latter, in most cases, inventory levels are obtained directly from certain of our largest wholesalers. Additionally, internal estimates are prepared based upon historical buying patterns and estimated end-user demand. Such information allows us to estimate the potential chargeback that we may ultimately owe to our customers given the quantity of inventory on hand. We continually monitor our provision for chargebacks and evaluate our reserve and estimates as additional information becomes available. A change of 5% in the estimated sell-through levels by our wholesaler customers and in the estimated wholesaler inventory levels would have an effect on our reserve balance of approximately \$34 million.

Returns — Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. Although application of the policy varies from country to country in accordance with local practices, generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. The majority of our product returns occur as a result of product dating, which falls within the range set by our policy, and are settled through the issuance of a credit to our customer. Although the introduction of additional generic competition does not give our customers the right to return product outside of our established policy, we do recognize that such competition could ultimately lead to increased returns. We analyze this on a case-by-case basis, when significant, and make adjustments to increase our reserve for product returns as necessary. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customers may return product. This period is known by us based on the shelf lives of our products at the time of shipment. Additionally, we consider factors such as levels of inventory in the distribution channel, product dating and expiration period, size and maturity of the market prior to a product launch, entrance into the market of additional generic competition, changes in formularies or launch of over-the-counter products, and make adjustments to the provision for returns in the event that it appears that actual product returns may differ from our established reserves. We obtain data with respect to the level of inventory in the channel directly from certain of our largest customers. A change of 5% in the estimated product return rate used in our calculation of our return reserve would have an effect on our reserve balance of approximately \$12 million.

Business Acquisitions, Intangible Assets, Goodwill and Contingent Consideration

We account for acquired businesses using the purchase method of accounting, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The cost to acquire businesses has been allocated to the underlying net assets of the acquired businesses based on estimates of their respective fair values. Amounts allocated to acquired IPR&D are capitalized at the date of an acquisition and, at that time, such IPR&D assets have indefinite lives. As products in development are approved for sale, amounts will be allocated to product rights and licenses and will be amortized over their estimated useful lives. Definite-lived intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. Because this process involves management making estimates with respect to future sales volumes, pricing, new product launches, government reform actions, anticipated cost environment and overall market conditions, and because these estimates form the basis for the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

We record contingent consideration resulting from a business acquisition at its estimated fair value on the acquisition date. Each reporting period thereafter, we revalue these obligations and record increases or decreases in their fair value as an adjustment to contingent consideration expense within the Consolidated Statements of Operations. Changes in the fair value of the contingent consideration obligations can result from adjustments to the discount rates, payment periods and adjustments in the probability of achieving future development steps, regulatory approvals, market launches, sales targets and profitability. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

Significant judgment is employed in determining the assumptions utilized as of the acquisition date and for each subsequent measurement period. Accordingly, changes in assumptions described above, could have a material impact on our consolidated results of operations.

Goodwill and intangible assets, including IPR&D, are reviewed for impairment annually and/or when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Impairment of goodwill and indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the net assets being tested. Impairment of definite-lived intangibles is determined to exist when undiscounted cash flows related to the assets are less than the carrying value of the assets being tested. Future events and decisions may lead to asset impairment and/or related costs.

Goodwill is allocated and evaluated for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment. Mylan has four reporting units, of which three are included in the Generics segment with the remaining reporting unit consisting of our Specialty segment. As of the date of our most recent annual impairment test, April 1, 2014, approximately 91% of Mylan's total goodwill is allocated to the three reporting units within the Generics segment as follows: North America (\$764.3 million), Europe (\$1.22 billion) and Rest of World (\$1.98 billion), with \$349.1 million allocated to our Specialty segment and reporting unit.

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 350, we have performed our annual impairment test as of April 1, 2014 utilizing the two-step goodwill impairment analysis referred to as "Step 1" and, if necessary, "Step 2". Step 1 of the impairment analysis consists of a comparison of the estimated fair value of the individual reporting units with their carrying amount, including goodwill. In estimating each reporting unit's fair value, we performed extensive valuation analysis, utilizing both income and market-based approaches, in our goodwill assessment process. We utilized an average of the two methods in estimating the fair value of the individual reporting units, except for the Specialty reporting unit. For the reporting units in which we utilized an average of the income and market-based approaches, the averaging of the two valuation methods did not significantly impact the estimated fair value of the reporting units. Given the variability in expectations for the Specialty reporting unit's product portfolio, an income based approach was utilized. The following describes the valuation methodologies used to derive the estimated fair value of the reporting units.

Income Approach: Under this approach, to determine fair value, we discounted the expected future cash flows of each reporting unit. We used a discount rate, which reflected the overall level of inherent risk and the rate of return an outside investor would have expected to earn. To estimate cash flows beyond the final year of our model, we used a terminal value approach. Under this approach, we used estimated earnings before interest, taxes, depreciation and amortization ("EBITDA") in the final year of our model, adjusted to estimate a normalized cash flow, applied a perpetuity growth assumption, and discounted by a perpetuity discount factor to determine the terminal value. We incorporated the present value of the resulting terminal value into our estimate of fair value.

Market-Based Approach: The Company also utilizes a market-based approach to estimate fair value, principally utilizing the guideline company method which focuses on comparing our risk profile and growth prospects to a select group of publicly traded companies with reasonably similar guidelines.

The Company performed its annual impairment test as of April 1, 2014, and the estimated fair value of the four reporting units, described above, were in excess of the respective carrying values of each reporting unit. For the North America reporting unit, the estimated fair value of this business exceeded its carrying value by over 100%. As it relates to the income approach for the North America reporting unit at April 1, 2014, we forecasted cash flows for the next ten years. During the forecast period, the revenue compound annual growth rate ("CAGR") was approximately 10%. A terminal value year was calculated with a 3% revenue growth rate applied. The CAGR in EBITDA margins was approximately 2%. The discount rate utilized was 8.5%. Under the market-based approach, we utilized an estimated range of market multiples of 10.5 to 13.0 times EBITDA plus a control premium of 15%.

As it relates to the income approach for the Europe reporting unit at April 1, 2014, we forecasted cash flows for the next ten years. During the forecast period, the revenue CAGR was approximately 6%. A terminal value year was

calculated with a 3% revenue growth rate applied. The CAGR in EBITDA margins was approximately 8%. The discount rate utilized was 9.0%. Under the market-based approach, we utilized an estimated range of market multiples of 10.0 to 12.0 times EBITDA plus a control premium of 15%. The estimated fair value of the Europe reporting unit exceeded its carrying value by approximately 18%.

For Rest of World reporting unit, the estimated fair value of this business exceeded its carrying value by approximately 20% as of April 1, 2014. As it relates to the income approach for Rest of World reporting unit, we forecasted cash flows for the next ten years. During the forecast period, the revenue CAGR was approximately 11%. A terminal value year was calculated with a 4% revenue growth rate applied. The CAGR in EBITDA margins was approximately 7% over the period of estimated cash flows. The discount rate utilized was 11.5%. Under the market-based approach, we utilized an estimated range of market multiples of 9.5 to 12.5 times EBITDA plus a control premium of 15%.

For the Specialty reporting unit, the estimated fair value of this business exceeded its carrying value by over 100% as of April 1, 2014. As it relates to the income approach for the Specialty reporting unit, we forecasted cash flows for the next ten years. During the forecast period, the revenue CAGR was a decline of approximately 3%. A terminal value year was calculated with a 3% revenue growth rate applied. EBITDA margins remained relatively stable at approximately 53% over the period of estimated cash flows. The discount rate utilized was 13.0%. Due to the variability in expectations for the Specialty reporting unit's product portfolio, primarily related to forecasted sales of the EpiPen® Auto-Injector and the potential generic competition, a market-based approach was not utilized for this reporting unit. The determination of the fair value of the reporting units requires us to make significant estimates and assumptions that affect the reporting unit's expected future cash flows. These estimates and assumptions primarily include, but are not limited to, market multiples, control premiums, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. In addition, changes in underlying assumptions, especially as it relates to the key assumptions detailed, could have a significant impact on the fair value of the reporting units.

In the event the estimated fair value of a reporting unit is less than the carrying value, additional analysis would be required. The additional analysis would compare the carrying amount of the reporting unit's goodwill with the implied fair value of that goodwill. The implied fair value of goodwill is the excess of the fair value of the reporting unit over the fair value amounts assigned to all of the assets and liabilities of that unit as if the reporting unit was acquired in a business combination and the fair value of the reporting unit represented the purchase price. If the carrying value of goodwill exceeds its implied fair value, an impairment loss equal to such excess would be recognized, which would likely materially impact the Company's reported results of operations.

We have also assessed the recoverability of certain long-lived assets contained within the reporting units. Any impairment of these assets must be considered prior to our impairment review of goodwill. The assessment for impairment is based on our ability to recover the carrying value of the long-lived assets by analyzing the expected future undiscounted pre-tax cash flows specific to the asset grouping.

We assess the recoverability of the carrying value of long-lived assets at the lowest level for which identifiable undiscounted cash flows are largely independent of the cash flows of other assets and liabilities. For Rest of World and Europe reporting units, this assessment is generally performed at the country level within the reporting units. If these undiscounted cash flows are less than the carrying value of long-lived assets within the asset group, an impairment loss is measured based on the difference between the estimated fair value and carrying value. Significant management judgment is involved in estimating the recoverability of these assets and is dependent upon the accuracy of the assumptions used in making these estimates, as well as how the estimates compare to the eventual future operating performance of the specific asset grouping. The Company's Australia operation in Rest of World reporting unit and certain asset groupings in the Europe reporting unit, principally Portugal, Belgium and Germany, remain at risk for potential impairment charges if the projected operating results are not achieved. Any future long-lived assets impairment charges would likely materially impact the Company's reported results of operations.

Income Taxes

We compute our income taxes based on the statutory tax rates and tax planning opportunities available to Mylan in the various jurisdictions in which we generate income. Significant judgment is required in determining our income taxes and in evaluating our tax positions. We establish reserves in accordance with Mylan's policy regarding accounting for uncertainty in income taxes. Our policy provides that the tax effects from an uncertain tax position be recognized in Mylan's financial statements, only if the position is more likely than not of being sustained upon audit, based on the technical merits of the position. We adjust these reserves in light of changing facts and circumstances, such as the settlement of a tax audit. Our provision for income taxes includes the impact of reserve provisions and changes to reserves. Favorable resolution would be recognized as a reduction to our provision for income taxes in the period of

resolution.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred in certain taxing jurisdictions over the three-year period ended December 31, 2014. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth.

Based on this evaluation, as of December 31, 2014, a valuation allowance of \$304.5 million has been recorded in order to measure only the portion of the deferred tax asset that more likely than not will be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period

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are reduced or if objective negative evidence in the form of cumulative losses is no longer present and additional weight may be given to subjective evidence such as projections for growth.

The resolution of tax reserves and changes in valuation allowances could be material to Mylan's results of operations or financial condition. A variance of 5% between estimated reserves and valuation allowances and actual resolution and realization of these tax items would have an effect on our reserve balance and valuation allowance of approximately \$25 million.

Legal Matters

Mylan is involved in various legal proceedings, some of which involve claims for substantial amounts. An estimate is made to accrue for a loss contingency relating to any of these legal proceedings if it is probable that a liability was incurred as of the date of the financial statements and the amount of loss can be reasonably estimated. Because of the subjective nature inherent in assessing the outcome of litigation and because of the potential that an adverse outcome in a legal proceeding could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price, such estimates are considered to be critical accounting estimates.

A variance of 5% between estimated and recorded litigation reserves (excluding indemnified claims) and actual resolution of certain legal matters would have an effect on our litigation reserve balance of approximately \$2 million.

Recent Accounting Pronouncements

In May 2014, the FASB issued revised accounting guidance on revenue recognition that will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principal of this guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. This guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. This guidance is effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years and can be applied using a full retrospective or modified retrospective approach. The Company is currently assessing the impact of the adoption of this guidance on its business, financial condition, results of operations and cash flows.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency Exchange Risk

A significant portion of our revenues and earnings are exposed to changes in foreign currency exchange rates. We seek to manage this foreign exchange risk in part through operational means, including managing same currency revenues in relation to same currency costs and same currency assets in relation to same currency liabilities.

Foreign exchange risk is also managed through the use of foreign currency forward-exchange contracts. These contracts are used to offset the potential earnings effects from mostly intercompany foreign currency assets and liabilities that arise from operations and from intercompany loans. Mylan's primary areas of foreign exchange risk relative to the U.S. Dollar are the Euro, Indian Rupee, Japanese Yen, Australian Dollar, Canadian Dollar, Pound Sterling and Brazilian Real.

Our financial instrument holdings at year end were analyzed to determine their sensitivity to foreign exchange rate changes. The fair values of these instruments were determined as follows:

- foreign currency forward-exchange contracts — net present values
- foreign currency denominated receivables, payables, debt and loans — changes in exchange rates

In this sensitivity analysis, we assumed that the change in one currency's rate relative to the U.S. Dollar would not have an effect on other currencies' rates relative to the U.S. Dollar. All other factors were held constant.

If there were an adverse change in foreign currency exchange rates of 10%, the expected net effect on net income related to Mylan's foreign currency denominated financial instruments would not be material.

Interest Rate and Long-Term Debt Risk

Mylan's exposure to interest rate risk arises primarily from our U.S. Dollar borrowings and investments. We invest primarily on a variable-rate basis and we borrow on both a fixed and variable basis. In order to maintain a certain ratio of fixed to variable rate debt, from time to time, depending on market conditions, Mylan will use derivative financial instruments such as interest rate swaps to fix interest rates on variable-rate borrowings or to convert fixed-rate borrowings to variable interest rates.

As of December 31, 2014, Mylan's long-term borrowings consist principally of \$573.0 million notional value in Cash Convertible Notes and \$5.70 billion in Senior Notes, the 2014 Term Loan and the New Revolving Facility.

Generally, the fair value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. Prior to the consummation of the Transaction, the fair value of the Cash Convertible Notes fluctuated as the market value of our common stock fluctuates. In connection with the consummation of the Transaction, we and New Mylan executed a supplemental indenture that amended the indenture governing the Cash Convertible Notes so that the fair value of the Cash Convertible Notes fluctuate as the market value of New Mylan's ordinary shares fluctuates. As of December 31, 2014, the fair value of our Senior Notes was approximately \$5.03 billion and the fair value of our Cash Convertible Notes was approximately \$2.42 billion. A 100 basis point change in interest rates on Mylan's variable rate debt, net of interest rate swaps, would result in a change in interest expense of approximately \$19 million per year.

Investments

In addition to available-for-sale securities, investments are made in overnight deposits, highly rated money market funds and marketable securities with maturities of less than three months. These instruments are classified as cash equivalents for financial reporting purposes and have minimal or no interest rate risk due to their short-term nature.

ITEM 8. Financial Statements And Supplementary Data

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Management's Report on Internal Control over Financial Reporting

Management of Mylan Inc. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. In order to evaluate the effectiveness of internal control over financial reporting, management has conducted an assessment, including testing, using the criteria in Internal Control - Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

As a result of this assessment, management has concluded that the Company maintained effective internal control over financial reporting as of December 31, 2014 based on the criteria in Internal Control - Integrated Framework (2013) issued by COSO.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited the effectiveness of the Company's internal control over financial reporting. Deloitte & Touche LLP's opinion on the Company's internal control over financial reporting appears on page 81 of this Form 10-K.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mylan Inc.:

We have audited the accompanying consolidated balance sheets of Mylan Inc. and subsidiaries (the “Company”) as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive earnings, equity, and cash flows for each of the three years in the period ended December 31, 2014. Our audits also included the consolidated financial statement schedule listed in the Index at Item 15. These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and consolidated financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Mylan Inc. and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2014, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 2, 2015 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Pittsburgh, Pennsylvania

March 2, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Mylan Inc.:

We have audited the internal control over financial reporting of Mylan Inc. and subsidiaries (the "Company") as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and consolidated financial statement schedule as of and for the year ended December 31, 2014 of the Company and our report dated March 2, 2015 expressed an unqualified opinion on those consolidated financial statements and consolidated financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Pittsburgh, Pennsylvania

March 2, 2015

MYLAN INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In millions, except share and per share amounts)

	December 31, 2014	December 31, 2013
ASSETS		
Assets		
Current assets:		
Cash and cash equivalents	\$ 225.5	\$ 291.3
Accounts receivable, net	2,268.5	1,820.0
Inventories	1,651.4	1,656.9
Deferred income tax benefit	345.7	250.1
Prepaid expenses and other current assets	2,295.8	452.9
Total current assets	6,786.9	4,471.2
Property, plant and equipment, net	1,785.7	1,665.5
Intangible assets, net	2,347.1	2,517.9
Goodwill	4,049.3	4,340.5
Deferred income tax benefit	83.4	77.8
Other assets	834.2	2,221.9
Total assets	\$ 15,886.6	\$ 15,294.8
LIABILITIES AND EQUITY		
Liabilities		
Current liabilities:		
Trade accounts payable	\$ 905.6	\$ 1,072.8
Short-term borrowings	330.7	439.8
Income taxes payable	160.7	49.7
Current portion of long-term debt and other long-term obligations	2,474.4	3.6
Deferred income tax liability	0.2	1.5
Other current liabilities	1,434.1	1,396.6
Total current liabilities	5,305.7	2,964.0
Long-term debt	5,732.8	7,586.5
Other long-term obligations	1,336.7	1,269.1
Deferred income tax liability	235.4	515.3
Total liabilities	12,610.6	12,334.9
Equity		
Mylan Inc. shareholders' equity		
Common stock — par value \$0.50 per share		
Shares authorized: 1,500,000,000		
Shares issued: 546,658,507 and 543,978,030 as of December 31, 2014 and December 31, 2013	273.3	272.0
Additional paid-in capital	4,212.8	4,103.6
Retained earnings	3,614.5	2,685.1
Accumulated other comprehensive loss	(987.0)	(240.1)
	7,113.6	6,820.6
Noncontrolling interest	20.1	18.1
Less: Treasury stock — at cost		
Shares: 171,435,200 and 172,373,900 as of December 31, 2014 and December 31, 2013	3,857.7	3,878.8
Total equity	3,276.0	2,959.9

Total liabilities and equity	\$ 15,886.6	\$ 15,294.8
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See Notes to Consolidated Financial Statements

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MYLAN INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(In millions, except per share amounts)

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
Net sales	\$7,646.5	\$6,856.6	\$6,750.2
Other revenues	73.1	52.5	45.9
Total revenues	7,719.6	6,909.1	6,796.1
Cost of sales	4,191.6	3,868.8	3,887.8
Gross profit	3,528.0	3,040.3	2,908.3
Operating expenses:			
Research and development	581.8	507.8	401.3
Selling, general and administrative	1,625.7	1,408.5	1,392.4
Litigation settlements, net	47.9	(14.6)	(3.1)
Other operating (income) expense, net	(80.0)	3.1	8.3
Total operating expenses	2,175.4	1,904.8	1,798.9
Earnings from operations	1,352.6	1,135.5	1,109.4
Interest expense	333.2	313.3	308.7
Other expense (income), net	44.9	74.9	(3.5)
Earnings before income taxes and noncontrolling interest	974.5	747.3	804.2
Income tax provision	41.4	120.8	161.2
Net earnings	933.1	626.5	643.0
Net earnings attributable to the noncontrolling interest	(3.7)	(2.8)	(2.1)
Net earnings attributable to Mylan Inc. common shareholders	\$929.4	\$623.7	\$640.9
Earnings per common share attributable to Mylan Inc. common shareholders:			
Basic	\$2.49	\$1.63	\$1.54
Diluted	\$2.34	\$1.58	\$1.52
Weighted average common shares outstanding:			
Basic	373.7	383.3	415.2
Diluted	398.0	394.5	420.2