Mylan N.V.
Form 10-K
February 16, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-K

þ Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended December 31, 2015

OR

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to .

Commission file number 333-199861

MYLAN N.V.
(Exact name of registrant as specified in its charter)

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

Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England
(Address of principal executive offices)
+44 (0) 1707-853-000
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

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

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

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

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

INCORPORATED BY REFERENCE

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

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PART I

ITEM 1. Business

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

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

Overview

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

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

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

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

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

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

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

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

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

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

Our Operations

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

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Our global operational footprint, including the locations of our manufacturing and R&D facilities and capabilities, along with the individual site's primary activities, are detailed on the map below.

Our global manufacturing platform is an important component of our business model. We own seven production, distribution and warehousing facilities in the U.S. including 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 and France. Through our manufacturing facilities in which we operate around the globe, we have a manufacturing capacity capable of producing approximately 65 billion oral solid doses, 3,600 kiloliters of APIs, 500 million injectable units, 260 million patches and 15 million semisolid units per year.

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 (the "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, Hyderabad, India and Sandwich, U.K. We also have specific technology focused development sites in Vermont, Ireland, India and Japan.

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

Our Generics segment primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule, injectable, transdermal patch, gel, cream or ointment form, as well as API. For the year ended December 31, 2015, Generics segment third party net sales were $8.16 billion. Our Generics segment operates within three geographical regions: North America, Europe and Rest of World. The chart below reflects third party net sales by region for the year ended December 31, 2015.

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North America

Of our broad global product portfolio of more than 1,400 products, we market approximately 610 of these products throughout North America. The U.S. generics market is the largest in the world, with generic prescription sales of $61.3 billion for the twelve months ended November 2015. In terms of generic prescription volume, approximately 77% of all pharmaceutical products sold in the U.S. are generic products, which demonstrates the high level of generic penetration in this market. Mylan holds the number two ranking in the U.S. generics prescription market both in terms of sales and prescriptions dispensed. Approximately one in every 13 prescriptions dispensed in the U.S. is a Mylan product. Our sales of products in the U.S. are derived primarily from the sale of oral solid dosages, injectables, transdermal patches, gels, creams, ointments and unit dose offerings. In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 430 products, of which approximately 330 are in capsule or tablet form, in an aggregate of approximately 950 dosage strengths. Included in these totals are approximately 50 extended-release products in a total of approximately 125 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 70 injectable branded and generic products, in an aggregate of approximately 90 dosage strengths. As of December 31, 2015, approximately 108 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, we market approximately 165 generic products in a total of approximately 340 dosage strengths from our U.S. product portfolio under supply and distribution agreements with wholesalers. Also, included in our U.S. product portfolio are seven transdermal patch products in approximately 30 dosage strengths, including our Fentanyl Transdermal System.

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 generics 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. Throughout Mylan's history, 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 FDA first-to-file status with Paragraph IV certification. As described further in the "Product Development and Government Regulation" discussion below, a first-filed ANDA with a Paragraph IV certification qualifies the product approval holder for a period of generic marketing and distribution exclusivity.

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In Canada, we have successfully leveraged the acquired EPD Business allowing us to further broaden our presence in this market. We currently rank seventh in terms of market share in the generic prescription market and Mylan products are sold in eight out of ten pharmacies in Canada. 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 collective Mylan brand to foster continued brand awareness and growth throughout the region.

Europe

Our generic pharmaceutical sales in Europe are generated primarily by our wholly owned subsidiaries, through which we have operations in 27 countries. Of our broad global product portfolio of more than 1,400 products, we market approximately 830 of these products throughout Europe. 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.

In Europe, the manner in which products are marketed 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.

The European generic prescription market also 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 68% and 74% of total prescription market sales in the twelve months ended November 2015, based on volume. Conversely, other major European markets, including France, Italy and Spain, are characterized by much lower generic penetration, ranging between 20% and 42% of total prescription sales in the twelve months ended November 2015, based on volume. However, actions taken by governments, particularly in these latter under-penetrated countries, to reduce healthcare 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.

As a result of the acquired EPD Business, Mylan has significantly expanded and strengthened its presence in Europe. In particular, we have grown our presence in several markets in Central and Eastern Europe, including Poland, Greece, the Czech Republic and Slovakia and gained access into new markets, such as Romania, Bulgaria, the Baltics and the Balkan States. Of the top ten generic prescription markets in Europe, we hold leadership positions in several of the markets, including the number one market share position in France and the number two market share position in Italy. In France, we have the highest market share in the generic market, with a share of approximately 28%. 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. In addition, the acquired EPD Business has allowed us to broaden our presence in this market by strengthening and growing our relationships with general practitioners and pharmacists, our primary customers in this market.

In Italy, we have the second highest market share in the company-branded generic prescription market, with a share of approximately 19% in terms of volume and value. We believe that the Italian generic market is still 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.

In addition to France and Italy, the acquired EPD Business has further grown our presence in several European markets including the U.K., Spain and markets in Eastern Europe. In the U.K., Mylan is ranked third in the U.K. generic prescription market, in terms of value, with an estimated market share of approximately 8%. 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 acquisition of the EPD Business in the U.K. has provided us with an additional branded off-patent market presence, particularly in the areas of pancreatic enzyme replacement therapy and hormone replacement therapy. The U.K. generic prescription market is highly competitive, and any growth in the market will stem from new product launches; however, we do expect that the value will continue to be affected by price erosion.

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In Spain, we have the seventh highest market share in the company-branded generic prescription market. The company-branded generic market comprised approximately 35% of the total Spanish pharmaceutical market by volume for the twelve months ended November 2015. Within the overall Spanish pharmaceutical market, our position has expanded due to the acquired EPD Business. We view further generic utilization and penetration of the Spanish market to be a key driver of our growth in this country.

We have a notable presence in other European generic prescription markets, including Portugal and Belgium, where we hold the third and fifth highest market share, respectively, in terms of value. In the Netherlands, we have the fourth highest market share in the generic prescription market, which is characterized by relatively high generic penetration.

Rest of World

We market generic pharmaceuticals in Rest of World through our subsidiaries in India, Australia, Japan, New Zealand and Brazil. Additionally, we have an export business which is focused on countries in Africa and emerging markets throughout the world, and through Mylan India, we market API to third parties and also supply other Mylan subsidiaries. Of our broad global product portfolio of more than 1,400 products, we market approximately 640 of these products throughout Rest of World.

The Indian generics market is the second largest in the world, behind the U.S., in terms of volume. In India, we are one of the world's largest API manufacturers as measured by the number of drug master files (“DMFs”) filed with regulatory agencies. Mylan India’s manufacturing capabilities include a range of dosage forms, such as tablets, capsules and injectables, in a wide variety of therapeutic categories. Mylan India has nine API and intermediate manufacturing facilities, eight oral solid dose (“OSD”) facilities and eight injectable facilities, for a total of sixteen finished dosage form (“FDF”) facilities, all located in India. Our presence in India goes beyond manufacturing, sales and marketing. With a global R&D center of excellence in Hyderabad, India and technology driven R&D sites in Bangalore, India and Ahmedabad, India, we are able to create unique and efficient R&D capabilities.

Mylan India markets high quality API to third parties around the world and ARV products for people living with HIV/AIDS. In addition, Mylan India has a growing commercial presence, our current franchises include Critical Care, Hepato Care, HIV Care, Onco Care and Women’s Care. We have expanded our products from therapeutic categories such as oncology and critical care. In November 2015, we completed our acquisition of Jai Pharma Limited, which significantly broadened our women’s care portfolio and strengthened our technical capabilities in terms of dedicated hormone manufacturing.

In Australia, we have the highest market share in the generic pharmaceutical market, with an estimated 32% market share by volume. Mylan is the number one supplier by volume to Australia’s national pharmaceuticals program. The acquired EPD Business has enabled Mylan to broaden its product portfolio in this market. The generic pharmaceutical market in Australia had sales of approximately $1.4 billion during the twelve months ended November 2015.

Japan is the second largest pharmaceutical market in the world by value, behind the U.S., and the sixth largest generic prescription market worldwide by value, with sales of approximately $6.0 billion during the twelve months ended November 2015. Beginning in 2013, we established an exclusive long-term strategic collaboration with Pfizer Japan Inc. (“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, under the agreement, 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. The Japanese government has stated that it now intends to grow the generic share to at least 70% by mid-2017 and to at least 80% at the earliest possible date between 2018 and the end of 2020. As of July 2015, the generic share reached 58%, up from approximately 55% in July 2014.

With the acquisition of the EPD Business, we have strengthened our position in the Japanese market as we have acquired a wide portfolio of branded products that are promoted by our own sales force. The acquired EPD Business is run independently from our strategic collaboration with Pfizer Japan.

We also have two manufacturing facilities located in Japan, which play a key role in supplying our businesses throughout the country. Currently, the market in Japan 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.

In addition to our operations in India, Australia and Japan, we also have a notable presence in New Zealand and a growing presence in Brazil. In New Zealand, we are the largest generics company in the country, with 31.5% of the market

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share by volume. New Zealand is generally a government tender market where pharmaceutical suppliers can gain exclusivity of up to three years. In New Zealand, we have broadened our market presence and profile with the addition of the acquired EPD Business. In Brazil, 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. Brazil is the third largest generic pharmaceutical market in the world, behind the U.S. and combined European market, in terms of value. In the coming years, the Brazilian generic pharmaceutical market is expected to continue its growth trajectory primarily because of the increase of off patent reference drugs, the growth of biological products and the growth of emerging markets. Our goal is to continue to build upon this local platform in order to further access the nearly $8 billion Brazilian generic pharmaceutical market.

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. For the year ended December 31, 2015, Specialty third party net sales were $1.20 billion. 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. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached $1 billion in annual net sales for the second year in a row.

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 a 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® Auto-Injector 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 holds 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 additional products to market.

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 are generally 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 are typically 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.

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Generic pharmaceutical products are the pharmaceutical and therapeutic equivalents of an approved brand drug, known as the reference listed drug ("RLD") that is 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 generally requires that similarity to an RLD, including bioequivalence, be demonstrated, any patents on the RLD have expired or been found to be invalid or not infringed, and any market exclusivity periods related to the RLD have ended. Because approved generic drugs have been found to be the same as their respective RLDs, they can be expected to have the same safety and effectiveness profile as the RLD. 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 four types of applications used for obtaining FDA approval of new products:

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.

Biologics License Application ("BLA") — A BLA is similar to an NDA, but is submitted to seek approval to market a drug product that is a biologic, which generally is a product derived from a living organism.

Biosimilars Application — This is an abbreviated approval pathway for a biologic product is that is "highly similar" to a product previously approved under a BLA.

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. An ANDA also typically must show that the proposed generic product is the same as the RLD in terms of active ingredient(s), strength, dosage form, route of administration and labeling.

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. Generally, if the patent owner brings an infringement action within 45 days from receiving 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 substantially complete ANDA containing 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.

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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 (or in some cases, accept for review) an application for a generic version product. If the reference drug is a new chemical entity (which generally means the active moiety has not previously been approved), 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 from the date of approval of the NDA or supplement. 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 Biologics Price Competition and Innovation Act (“BPCIA”) authorizes the FDA to license a biological product that is a “biosimilar” to an FDA-licensed biologic through an abbreviated pathway. The BPCIA establishes criteria for determining that a product is biosimilar to an already licensed biologic, known as the “reference product,” and establishes a process by which an abbreviated BLA for a biosimilar product is submitted, reviewed and approved. This abbreviated approval pathway is intended to permit a biosimilar product to come to market more quickly and less expensively than if a full BLA were submitted, by relying to some extent on FDA’s previous review and approval of the reference product. Generally, a biosimilar must be shown to be highly similar to, and have no clinically meaningful differences in safety, purity or potency from, the reference product. The BPCIA provides periods of exclusivity that protect a reference product from biosimilars competition. Under the BPCIA, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar may not be licensed until twelve years after the reference product’s approval. Additionally, the BPCIA establishes procedures by which the biosimilar applicant must provide information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval. The BPCIA also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product.

Because the BPCIA is a relatively new law, we anticipate that its contours will be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including FDA issuance of guidance documents, proposed regulations, and decisions in the course of considering specific applications. In that regard, FDA has to date issued various guidance documents and other materials providing indications of the agency’s thinking regarding any number of issues implicated by the BPCIA. Additionally, FDA’s approval in 2015 of the first biosimilar application helps define the agency’s approach to certain issues.

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.

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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 approval process for all generic pharmaceuticals has two tracks that may proceed in parallel. The first track involves an examination of the product by Health Canada, the agency responsible for national public health, to ensure that the quality, safety and efficacy of the product have been established. Second persons (i.e. generic companies) may seek approval to sell a product by submitting an abbreviated new drug submission ("ANDS") to Health Canada to demonstrate that its product is bioequivalent to the brand reference product already marketed in Canada under a Notice of Compliance ("NOC"). When Health Canada is satisfied with the quality, safety and efficacy described in the ANDS, it issues a NOC for that product, subject to any brand patents 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 (the "originator") may list patents relating to the medicinal ingredient, formulation, dosage form or the use of the drug on the Patent Register. Where a generic applicant makes direct or indirect reference in its ANDS to a brand product for which there are patents listed on the Patent Register, the generic must make at least one of the statutory allegations with respect to each patent listed (e.g. that the generic will await patent expiry, or the patent is invalid and/or would not be infringed). If the generic challenges the listed patent, it is required to serve the originator with a Notice of Allegation ("NOA"), which gives a detailed statement of the factual and legal basis for its allegations. If the originator wishes to seek an order prohibiting the issuance of the NOC to the generic, it must commence a court application within 45 days after it has been served with the NOA. Once an application is commenced, Health Canada may not issue a NOC until the earlier of the determination of the proceeding by the court, or the expiration of 24 months. To obtain a prohibition order, the originator must satisfy the court that the generics' allegations of invalidity and or non-infringement are not justified.

Section C.08.004.1 of the Canadian Food and Drug Regulations is the so-called data protection provision. A generic applicant does not need to perform duplicate clinical trials similar to those conducted by the first NOC holder (i.e. the brand), but is permitted to demonstrate safety and efficacy by submitting data demonstrating that its formulation is bioequivalent to the approved brand formulation. 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 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 after the issuance of the first NOC, and cannot receive ultimate approval for an additional two years. If the first NOC holder also conducts clinical trials 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 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.

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

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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

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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 healthcare 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

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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 2015, a negative impact on sales and gross profit in this market.

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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 amended PMDL.

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 reexamination 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

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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 all products and services that affect the health of the population are regulated by the National Agency of Sanitary Surveillance ("ANVISA"), created by Law No. 9,782, of January 26, 1999. ANVISA is a governmental body directly linked to the Ministry of Health and is part of the Unified Health System, responsible for the sanitary control of production, storage, distribution, importation and marketing of products and services subject to sanitary surveillance. ANVISA is also 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. ANVISA regularly monitors the market's economic regulations and is responsible for the price control of pharmaceutical drugs.

Active Pharmaceutical Ingredients

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;

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- submission of an NDA or BLA 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 or BLA.

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 or BLA. The NDA/BLA 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 have separate pharmaceutical regulatory bodies, including, but not limited to, the National Agency for Medicines and Health Products in France, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the U.K., the EMA (a decentralized body of the EU), the Federal Institute for Drugs and Medical Devices in Germany, the Irish Medicines Board in Ireland, the Italian Medicines Agency, the Spanish Agency of Medicines and Medical Devices, 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;

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- 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 (which are regulated as biologics);
- completion of additional preclinical and clinical studies for approved NDA products required by the FDA, known as post-approval (Phase IV) commitments; and
- conducting life-cycle management studies intended to further define the profile of products subject to pending or approved NDAs.

The success of biosimilars 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, 2015, we had approximately 4,109 marketing license approvals pending. During 2015, we completed 1,049 global country level product submissions, which included 41 in North America, 522 in Europe and 486 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, 2015, we received 731 individual country product approvals globally, which was equal to 1,205 approved new marketing licenses. Of those total individual country product approvals globally, there were 77 approvals in North America, including 56 in the U.S.; 396 approvals in Europe; and 258 approvals in Rest of World, of which 44 approvals were for ARV products. The 44 country level ARV approvals received consisted of 14 products in 13 different countries. The 56 approvals in the U.S. consisted of 45 final ANDA approvals and 11 tentative ANDA approvals. The 396 approvals in Europe covered 59 different products resulting in a total of 869 product marketing licenses. The 258 approvals in Rest of World included 222 approvals from emerging markets which represented 56 products in 45 countries.

As of December 31, 2015, we had 270 ANDAs pending FDA approval, representing approximately $101.5 billion in annual sales for the brand name equivalents of these products for the year ended December 31, 2015. Of those pending product applications, 50 were first-to-file Paragraph IV ANDA patent challenges, representing approximately $35.6 billion in annual brand sales for the year ended December 31, 2015. 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 $672 million, $582 million and $508 million for the years ended December 31, 2015, 2014 and 2013, 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 branded 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.

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.

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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 and mail order pharmacies. We also market our generic products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, pharmacy benefit management companies, GPOs and government entities. These customers, called "indirect customers," purchase our products primarily through our wholesale customers. In North America, wholesalers, retail drug chains and managed care organizations, pharmacy benefits managers (collectively, "payers") 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 is sold primarily to generic FDF manufacturers throughout the world, as well as to other Mylan subsidiaries.

Following the acquisition of the acquired EPD Business, we launched a comprehensive advertising campaign called "Better health for a better world™." The campaign represents Mylan's promise for the future as we transform into a

healthcare company by setting new standards in the industry and providing 7 billion people access to high quality medicine, one person at a time. The campaign's goals are to educate consumers and customers about Mylan and to help ensure a smooth transition as we continue integrating the acquired EPD Business's products into our portfolio. We have launched the campaign in approximately 25 non-U.S. developed markets and, during 2016, plan to introduce the campaign in more than 40 additional countries.

Specialty Segment

Mylan Specialty markets its products to a number of different customer audiences in the U.S., including healthcare practitioners, wholesalers, pharmacists and pharmacy chains, hospitals, payers, pharmacy benefit manager, health maintenance

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organizations ("HMOs"), home healthcare, long-term care and patients. We reach these customers through our field-based sales force and National Accounts team, to increase our customers' understanding of the unique clinical characteristics and benefits of our branded products. Additionally, Mylan Specialty supports educational programs to consumers, physicians and patients.

Over the past few years, we have successfully championed and expanded legislation and policies that allow or require schools to stock epinephrine auto-injectors. In August 2012, we launched the EpiPen4Schools® program, providing U.S. schools free EpiPen® Auto-Injectors along with educational training resources. In November 2014, we announced a multi-year strategic alliance agreement with Walt Disney Parks and Resorts to help increase anaphylaxis awareness. As part of the collaboration we have introduced an educational website for families managing potentially life-threatening (severe) allergies and have developed a series of storybooks for families living with severe allergies, the first of which was distributed in 2015. Mylan also sponsors activities with advocacy groups in the severe allergy space, including the Food Allergy Research and Education ("FARE") Walks, and launched a branded campaign, EpiPen® On Location, encouraging those living with severe allergies and their caregivers to understand the importance of avoiding allergic triggers and having access to two EpiPen® Auto-Injectors at all times.

Major Customers

The following table represents the percentage of consolidated third party net sales to Mylan's major customers during the years ended December 31, 2015, 2014 and 2013.

	Percentage of Third Party Net Sales		
	2015	2014	2013
AmeriSourceBergen Corporation	16 %	13 %	10 %
McKesson Corporation	15 %	19 %	14 %
Cardinal Health, Inc.	12 %	12 %	15 %

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:

North America

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 branded 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 branded 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.

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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 healthcare program, requires 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. Sales of Medicaid-reimbursed non-innovator products require manufacturers to rebate 13% of the average manufacturer's price and, effective 2017, adjusted by the Consumer Price Index-Urban (the "CPI-U") based on certain data. Sales of the Medicaid-reimbursed innovator or single-source products require manufactures to the rebate the greater of approximately 23% of the average manufacturer's price or the difference between the average manufacturer's price and the best price adjusted by the CPI-U based on certain data. We believe that federal or state governments will 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 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.

Europe

In France, generic penetration 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.

In Italy, the 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 as well as a specific legislative provision which requires them to propose generic products to patients, when available.

The U.K. is one of the most competitive off-patent 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 is a rapidly growing, highly fragmented generic market with many participants. As a result of legislative changes, all regions within Spain have moved, or will move, to INN prescribing and substitution, thus making the pharmacists the key driver of generic usage. Within the last few years, the Andalusia region, representing approximately 21% of the total retail market, has evolved into a tendering commercial model. 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 markets in the Netherlands and Germany have become highly competitive as a result of a large number of generic players, both having one of the highest generic penetration rates in Europe and the continued use of tender systems. Under a tender system, health insurers are entitled to issue invitations to tender products. Pricing pressures resulting from an effort to

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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.

Rest of World

In India, the commercial pharmaceutical 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. 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.

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

In Japan, government initiatives have historically 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.

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, including products in our Specialty segment and products within our Europe and Rest of World regions 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.

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Employees

As of December 31, 2015, Mylan's global workforce included nearly 35,000 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

Mylan maintains an Internet website at the following address: mylan.com. We make available on or through our website certain reports and amendments to those reports that Mylan files with the Securities and Exchange Commission (the "SEC") in accordance with the Securities Exchange Act of 1934 (the "Exchange Act"). These include our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. We make this information available on our website free of charge, as soon as reasonably practicable after electronically filed with, or furnished to, the SEC. The contents of our website are not incorporated by reference in this Report on Form 10-K and shall not be deemed "filed" under the Exchange Act.

The public may also read and copy any materials that we 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).

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.

Risks Related to the Business of Mylan

ABBOTT'S SUBSIDIARIES THAT HOLD ORDINARY SHARES ARE COLLECTIVELY A SIGNIFICANT BENEFICIAL SHAREHOLDER OF OURS AND THE PRESENCE OF A SIGNIFICANT BENEFICIAL SHAREHOLDER MAY AFFECT THE ABILITY OF OUR OTHER SHAREHOLDERS TO EXERCISE INFLUENCE OVER US, ESPECIALLY IN LIGHT OF CERTAIN VOTING OBLIGATIONS UNDER OUR SHAREHOLDER AGREEMENT WITH ABBOTT AND ITS SUBSIDIARIES.

Abbott's subsidiaries currently own approximately 14.2% of our outstanding ordinary shares. The shares owned by Abbott's subsidiaries are subject to the terms of a shareholder agreement, which requires the Abbott subsidiaries to vote in favor of the director nominees recommended by our board of directors and in accordance with the recommendation of our board of directors on all other matters, subject to certain exceptions for extraordinary transactions. This voting agreement is in force with respect to ordinary shares owned by Abbott's subsidiaries so long as they collectively beneficially own at least five percent of our issued and outstanding ordinary shares. Abbott's subsidiaries that hold ordinary shares are collectively a significant beneficial shareholder of ours. Having a significant beneficial shareholder that is required in many instances to vote with the recommendation of our board of directors may make it more difficult for our other shareholders to exercise influence over most matters submitted to shareholders for approval, including the election of directors, issuances of securities for equity compensation plans, amendments to the Articles, and shareholder proposals submitted pursuant to Rule 14a-8 of the Exchange Act. Additionally, such Abbott subsidiaries are obligated, pursuant to a shareholder agreement, not to tender any ordinary shares in any tender or exchange offer that our board of directors recommends that the shareholders reject and, if our board of directors has recommended against a transaction, such Abbott subsidiaries are required to vote against such

transaction, which may have the effect of making it more difficult for a third party to acquire, or discouraging a third party from seeking to acquire, a majority of our outstanding ordinary shares in a public takeover offer, or control of our board of directors through a proxy solicitation.

PROVISIONS IN OUR GOVERNANCE ARRANGEMENTS OR THAT ARE OTHERWISE AVAILABLE UNDER DUTCH LAW COULD DISCOURAGE, DELAY, OR PREVENT A CHANGE IN CONTROL OF US AND MAY AFFECT THE MARKET PRICE OF OUR ORDINARY SHARES.

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Some provisions of our governance arrangements that are available under Dutch law, such as our grant to a Dutch foundation (stichting) of a call option to acquire preferred shares to safeguard the interests of the Company, its businesses and its stakeholders against threats to our strategy, mission, independence, continuity and/or identity, may discourage, delay, or prevent a change in control of us, even if such a change in control is sought by our shareholders.

WE MAY BE FORCED TO DELIST, OR OTHERWISE CHOOSE TO DELIST, FROM THE TEL AVIV STOCK EXCHANGE IN THE FUTURE AND THIS COULD HAVE A NEGATIVE IMPACT ON OUR ORDINARY SHARE PRICE AND ON THE LIQUIDITY OF OUR ORDINARY SHARES.

On October 29, 2015, the Tel Aviv Stock Exchange (the "TASE") approved the listing of our ordinary shares on the TASE, and our ordinary shares began trading on the TASE on November 4, 2015. As a result, our ordinary shares are now listed on both the NASDAQ Global Select Stock Market ("NASDAQ") and the TASE. In connection with our offer to acquire Perrigo Company plc, we have undertaken that our ordinary shares will be listed on the TASE for a period of not less than one year from the date they first started trading on the TASE. We have also undertaken with the TASE that for as long as our ordinary shares are listed for trading on the TASE, if new Mylan preferred shares are issued, in response to the Dutch foundation (stichting) described above exercising its call option to acquire preferred shares or otherwise, we will take all necessary actions, as soon as practicable and no later than three Israeli business days following the issuance of such preferred shares, to notify the TASE that we are delisting our ordinary shares from the TASE (with such delisting to take effect 90 days later). Accordingly, there can be no guarantee as to how long our ordinary shares will continue to be listed on the TASE. If we delist from the TASE, that could have a negative impact on our ordinary share price and on the liquidity of our ordinary shares for our shareholders, particularly in Israel.

WE DO NOT ANTICIPATE PAYING DIVIDENDS FOR THE FORESEEABLE FUTURE, AND OUR SHAREHOLDERS MUST RELY ON INCREASES IN THE TRADING PRICE OF THE ORDINARY SHARES TO OBTAIN A RETURN ON THEIR INVESTMENT.

Mylan N.V. does not anticipate paying dividends in the immediate future. We anticipate that we will retain all earnings, if any, to support our operations and to pursue additional transactions to deliver additional shareholder value. Any future determination as to the payment of dividends will, subject to Dutch law requirements, be at the sole discretion of our board of directors and will depend on our financial position, results of operations, capital requirements, and other factors our board of directors deems relevant at that time. Holders of Mylan N.V.'s ordinary shares must rely on increases in the trading price of their shares to obtain a return on their investment in the foreseeable future.

THE MARKET PRICE OF THE ORDINARY SHARES MAY BE VOLATILE, AND THE VALUE OF YOUR INVESTMENT COULD MATERIALLY DECLINE.

Investors who hold Mylan N.V.'s ordinary shares may not be able to sell their shares at or above the price at which they purchased such shares. The share price of Mylan N.V.'s ordinary shares fluctuate materially from time to time, and we cannot predict the price of the ordinary shares at any given time. The risk factors described herein could cause the price of the ordinary shares to fluctuate materially. In addition, the stock market in general, including the market for generic and specialty pharmaceutical companies, has experienced price and volume fluctuations. These broad market and industry factors may materially harm the market price of the ordinary shares, regardless of our operating performance. In addition, the price of the ordinary shares may be affected by the valuations and recommendations of the analysts who cover us, and if our results do not meet the analysts' forecasts and expectations, the price of the ordinary shares could decline as a result of analysts lowering their valuations and recommendations or otherwise. In the past, following periods of volatility in the market and/or in the price of a company's stock, securities class-action litigation has often been instituted against other companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. We may issue additional ordinary shares upon the exercise of existing warrants, and we or our shareholders also may offer or sell our ordinary shares or securities convertible into or exchangeable or exercisable for ordinary shares. An increase in the number of the ordinary shares issued and outstanding and the possibility of sales of ordinary shares or securities convertible into or exchangeable or exercisable for ordinary shares may depress the future trading price of the

ordinary shares. In addition, if additional offerings occur, the voting power of our then existing shareholders may be diluted.

THE EPD TRANSACTION MAY NOT ACHIEVE ALL INTENDED BENEFITS OR MAY DISRUPT OUR PLANS AND OPERATIONS.

There can be no assurance that we will be able to successfully complete the integration of the acquired EPD Business with the business of Mylan Inc. or otherwise fully realize the expected benefits of the EPD Transaction. Our ability to fully

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realize the anticipated benefits of the EPD Transaction will depend, to a large extent, on our ability to integrate the acquired EPD Business with the business of Mylan Inc. and realize the benefits of the combined business. The combination of two independent businesses is a complex, costly, and time-consuming process. Our business may be negatively impacted if we are unable to effectively manage its expanded operations. The integration is ongoing and continues to require significant time and focus from management and may divert attention from the day-to-day operations of our business. Additionally, the integration of the businesses could disrupt our plans and operations, which could delay the achievement of our strategic objectives.

The expected synergies and operating efficiencies of the EPD Transaction may not be fully realized, which could result in increased costs and have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary 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 acquired EPD Business with the business of Mylan Inc.;
- difficulties in the integration of operations and IT applications, including enterprise resource planning ("ERP") 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, and certain of its business partners, which includes agreements providing for transition services, development and manufacturing relationships, and license arrangements.

Many of these factors are outside of our 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 our business, financial condition, results of operations, cash flows, and/or ordinary 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. Furthermore, even if the operations of Mylan Inc. and the acquired EPD Business are integrated successfully, we may not realize the full benefits of the EPD 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 our earnings per share, decrease or delay the expected accretive effect of the EPD Transaction, and/or negatively impact the price of our ordinary shares.

WE EXPECT 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 (INCLUDING UNDER APPLICABLE INCOME TAX TREATIES), REGULATIONS, RULES, OR INTERPRETATIONS THEREOF APPLICABLE TO INVERTED COMPANIES AND THEIR AFFILIATES, WHETHER ENACTED BEFORE OR AFTER THE EPD TRANSACTION, MAY MATERIALLY ADVERSELY AFFECT US.

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 EPD Transaction. Changes to Section 7874 of the Internal Revenue Code (the "Code") or, to the U.S. Treasury Regulations promulgated thereunder, or interpretations thereof, or to other relevant tax laws (including applicable income tax treaties), could affect our status as a non-U.S. corporation for U.S. federal income tax purposes and the tax consequences to us and our affiliates. Any such changes could have prospective or retroactive application, and may apply even if enacted or promulgated now that the EPD Transaction has closed. If we were to be treated as a U.S. corporation for U.S. federal income tax purposes, or if the relevant tax laws (including applicable income tax treaties) change, we would likely be subject to significantly greater U.S. tax liability than currently contemplated as a non-U.S. corporation or if the relevant tax laws (including applicable income tax treaties) had not

changed.

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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 and November 19, 2015, the U.S. Treasury Department issued notices announcing its intention to promulgate certain regulations that will apply to inversion transactions completed on or after September 22, 2014.

In the notices, the U.S. Treasury Department also announced that it expects to issue additional guidance to further limit and reduce the benefits of 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 and on May 20, 2015, the U.S. Treasury Department announced its intention to revise certain provisions of the model income tax treaties, which, if ultimately adopted by the U.S. and relevant jurisdictions, could reduce potential tax benefits for us and our affiliates by imposing U.S. withholding taxes on particular payments from our U.S. affiliates to related and unrelated foreign persons. Any such future regulatory or legislative actions regarding inversion transactions or any other changes in relevant tax laws (including under applicable income tax treaties), 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 September 22, 2014, and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

THE IRS MAY NOT AGREE THAT WE SHOULD BE TREATED AS A NON-U.S. CORPORATION FOR U.S. FEDERAL INCOME TAX PURPOSES.

The U.S. Internal Revenue Service (the "IRS") may not agree that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes. Although we are not incorporated in the U.S. and expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes, the IRS may assert that we should be treated as a U.S. corporation for U.S. federal income tax purposes. 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.

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 among our subsidiaries are based upon internationally accepted standards and applicable law, 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 ordinary share price.

WE MAY NOT BE ABLE TO MAINTAIN COMPETITIVE FINANCIAL FLEXIBILITY AND OUR CORPORATE TAX RATE.

We believe that our structure and operations will give us the ability to achieve competitive financial flexibility and a competitive worldwide effective corporate tax rate. The material assumptions underlying our expected tax rates include the fact that we expect certain of our businesses will be operated outside of the U.S. and, as such, will be subject to a lower tax rate than operations in the U.S., which will result in a lower blended worldwide tax rate we were previously able to achieve. We must also make assumptions regarding the effect of certain internal reorganization

transactions, including various intercompany transactions. We cannot give any assurance as to what our effective tax rate will be, however, because of, among other reasons, uncertainty regarding the tax policies of the jurisdictions where we operate, potential changes of laws and interpretations thereof, and the potential for tax audits or challenges. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of the U.K., the Netherlands and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate. Such a material change could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

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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 ordinary 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 ordinary share price.

WE MAY BECOME TAXABLE IN A JURISDICTION OTHER THAN THE UNITED KINGDOM AND THIS MAY INCREASE THE AGGREGATE TAX BURDEN ON US.

Based on our current management structure and current tax laws of the United States, the United Kingdom, and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, the United Kingdom and the Netherlands competent authorities have determined that we are tax resident solely in the United Kingdom for the purposes of the Netherlands-U.K. tax treaty. We have received a binding ruling from the competent authorities in the United Kingdom and in the Netherlands confirming this treatment. We will therefore be tax resident solely in the United Kingdom so long as the facts and circumstances set forth in the relevant application letters sent to those authorities remain accurate. Even though we received a binding ruling, the applicable tax laws or interpretations thereof may change, or the assumptions on which such rulings were based may differ from the facts. As a consequence, we may become a tax resident of a jurisdiction other than the U.K. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

WE HAVE AND WILL INCUR DIRECT AND INDIRECT COSTS AS A RESULT OF OUR CORPORATE STRUCTURE.

We have incurred costs and expenses in connection with, and will incur further costs and expenses as a result of, becoming a Dutch company that is a tax resident of the United Kingdom. Certain costs are not readily ascertainable and are difficult to quantify and determine. These costs and expenses include professional fees associated with complying with Dutch corporate law and financial reporting requirements, professional fees associated with complying with the tax laws of the United Kingdom, and costs and expenses incurred in connection with holding a majority of the meetings of our board of directors and certain executive management meetings in the U.K., as well as any additional costs we may incur going forward as a result of our new corporate structure. These costs may materially exceed the costs historically borne by us, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

WE HAVE GROWN AT A VERY RAPID PACE AND EXPECT TO AGGRESSIVELY PURSUE ADDITIONAL ACQUISITION OPPORTUNITIES THAT MAKE FINANCIAL AND STRATEGIC SENSE FOR US. 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 ORDINARY SHARE PRICE.

We have grown very rapidly over the past several years as a result of increasing sales and several acquisitions and other transactions, and expect to aggressively pursue additional acquisition opportunities that make financial and strategic sense for

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us. We evaluate various strategic transactions and business arrangements, including acquisitions, asset purchases, partnerships, joint ventures, restructurings, divestitures and investments, on an ongoing basis. These transactions and arrangements may be material both from a strategic and financial perspective.

We are currently in the process of evaluating certain potential strategic transactions, including acquisitions, and we may choose to aggressively pursue one or more of these opportunities at any time. Some of these opportunities would be material if pursued and consummated. Our growth has, and will continue to, put significant demands on our processes, systems, and employees. 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 ordinary share price.

CURRENT AND CHANGING ECONOMIC CONDITIONS MAY ADVERSELY AFFECT OUR INDUSTRY, BUSINESS, PARTNERS AND SUPPLIERS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR ORDINARY 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 default on sovereign debt 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 reduced spending on healthcare, 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 healthcare, 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 ordinary 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, data privacy and security and 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 the Consumer Protection Act;
- changes in laws, regulations, and practices affecting the pharmaceutical industry and the healthcare system, including but not limited to imports, exports, manufacturing, quality, cost, pricing, reimbursement, approval, inspection, and delivery of healthcare;
- fluctuations in exchange rates for transactions conducted in currencies other than the functional currency;

- differing local product preferences and product requirements;

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- 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;
- 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 ordinary share price.

WE ARE SUBJECT TO THE U.S. FOREIGN CORRUPT PRACTICES ACT, U.K. BRIBERY 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, the U.K. Bribery 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 ordinary share price.

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 ORDINARY SHARE PRICE.

We are subject to various U.S. federal, state, and local and non-U.S. 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 ordinary 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

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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 ordinary share price.

CURRENCY FLUCTUATIONS AND CHANGES IN EXCHANGE RATES COULD ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR ORDINARY 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 non-U.S. 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 ordinary 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 healthcare 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. Terrorist attacks, military activity, rioting, or civil or political unrest 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 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 ordinary share price.

AN INABILITY TO IDENTIFY OR SUCCESSFULLY BID FOR SUITABLE ACQUISITION TARGETS, OR CONSUMMATE AND EFFECTIVELY INTEGRATE RECENT AND FUTURE POTENTIAL ACQUISITIONS, OR TO EFFECTIVELY DEAL WITH AND RESPOND TO UNSOLICITED BUSINESS PROPOSALS COULD LIMIT OUR FUTURE GROWTH AND HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, CASH FLOWS, AND/OR ORDINARY SHARE PRICE.

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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 company 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 or businesses 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.

In addition, in April 2015 we received an unsolicited and subsequently withdrawn non-binding expression of interest from Teva Pharmaceutical Industries Ltd. to acquire all of our outstanding shares and may receive similar proposals in the future. Such unsolicited business proposals may not be consistent with or enhancing to our financial, operational, or market strategies (which we believe have proven to be successful) and may not further the interests of our shareholders and other stakeholders, including employees, creditors, customers, suppliers, relevant patient populations and communities in which Mylan operates and may jeopardize the sustainable success of Mylan's business. However, the evaluation of and response to such unsolicited business proposals may nevertheless 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.

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 more profitable activities, 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 ordinary 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 ordinary 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 ORDINARY SHARE PRICE.

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Under 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;
- amortization of intangible assets acquired;
- a reduction in the useful lives of intangible assets acquired;
- 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 ordinary 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 other transactions 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 ordinary share price.

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

The pharmaceutical industry is subject to regulation by various governmental authorities. For instance, we must comply with applicable laws and requirements of the FDA and comparable regulatory agencies, including foreign authorities, in our other markets with respect to the research, development, manufacture, quality, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, pharmacovigilance, sale, distribution, import, export, marketing, advertising, and promotion of pharmaceutical products. Failure to comply with regulations of the FDA and other foreign regulators could result in a range of consequences, including, but not limited to, fines, penalties,

disgorgement, unanticipated compliance expenditures, suspension

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of review of applications or other submissions, 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, injunctions, and/or criminal prosecution. Under certain circumstances, a regulator may also have the authority to revoke or vary previously granted drug approvals.

The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information about any of our marketed or investigational products, those authorities may require labeling changes, establishment of a risk evaluation and mitigation strategy or similar strategy, restrictions on a product's indicated uses or marketing, or post-approval studies or post-market surveillance.

The FDA and comparable regulatory authorities also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and similar regulators in other countries. Products must be manufactured in our facilities in accordance with current good manufacturing practices ("cGMP") or similar standards in each territory in which we manufacture. Compliance with such regulations requires substantial expenditures of time, money, and effort in multiple areas, including training of personnel, record-keeping, production, and quality control and quality assurance. The FDA and other regulatory authorities, including foreign authorities, periodically inspect our manufacturing facilities for compliance with cGMP or similar standards in the applicable territory. Regulatory approval to manufacture a drug is granted on a site-specific basis. Failure to comply with cGMP 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 authorities, which could result in a receipt of an untitled or warning letter, fines, penalties, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, suspension of review of applications or other submissions, suspension of ongoing clinical trials, 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, orders to suspend, vary, or withdraw marketing authorizations, injunctions, consent decrees, requirements to modify promotional materials or issue corrective information to healthcare practitioners, refusal to permit import or export, criminal prosecution and/or other adverse actions.

If any regulatory body were to delay, withhold, or withdraw approval of an application; require a recall or other adverse product action; require one of our manufacturing facilities to cease or limit production; or suspend, vary, or withdraw related marketing authorization, 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 ordinary share price.

Although we have established 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 are unable to resolve these observations and address regulator's concerns in a timely fashion, our business, financial condition, results of operations, cash flows, and/or ordinary share price could be materially affected.

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. On August 6, 2015, the FDA issued a second warning letter regarding this facility, the Agila Onco Therapies Limited facility and the Agila Sterile Product Division facility. We are working to resolve this matter expeditiously and we continue to work closely with the FDA and other regulatory entities to address our improvements at all Agila facilities. No assurances can be provided that the resolution of the issues identified in the FDA's letters will not have a material adverse effect on our global injectables business. 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 ordinary share price.

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 ordinary share price.

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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 NEWLY ENACTED 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 REVENUE AND 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;
- 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 and regulations 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 ordinary share price.

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

Our future revenues and profitability will depend, in part, upon our ability to successfully and timely develop, license, or otherwise acquire and commercialize new generic products as well as branded pharmaceutical products protected by patent or statutory authority. Product development is inherently risky, especially for new drugs for which safety and efficacy have not

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been established and/or 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 ordinary 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 branded and generic pharmaceutical products is rigorous, time consuming, costly, and inherently 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, clinical, or other 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, for example, with respect to the indicated uses and delivery methods for which the drug may be marketed, or may include warnings, precautions or contraindications in the labeling, which could restrict our potential market for the drug. A regulatory approval may also include post-approval study or risk management requirements that may substantially increase the resources required to market 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 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 a "first applicant," that is the first submitted ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with the ANDA's reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be shared with other ANDAs filed on the same day, the FDA cannot grant final approval to later-submitted ANDAs for the same generic equivalent. If an ANDA is awarded 180-day 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. By contrast, if we are not a "first applicant" to challenge a listed patent for such a product, we may lose significant advantages to a competitor with 180-day exclusivity, even if we obtain FDA approval for our generic drug product. 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 the EU and other countries and regions, there is no exclusivity period for the first generic product. The European Commission or national regulatory agencies may grant marketing authorizations to any number of generics.

If we are unable to navigate our products through the approval process in a timely manner, there could be an adverse effect on our product introduction plans, business, financial condition, results of operations, cash flows, and/or ordinary 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

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primarily to enable us to gain approval for, manufacture, and market pharmaceuticals in accordance with applicable laws and 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 R&D costs in excess of what we anticipated. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. We or our partners may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned, or be completed on schedule, if at all.

Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons. If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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 ordinary share price.

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

Even if we are able to obtain regulatory approvals for our new generic or branded pharmaceutical products, 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, perceived advantages, and relative safety and efficacy of alternative products from our competitors;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- the prices of our products relative to those of our competitors;
- the timing of our market entry;
- the effectiveness of our marketing, sales, and distribution strategy and operations;
- other competitor actions; and
- the continued acceptance of and/or reimbursement for our products by government and private formularies and/or third party payors, as well as the willingness and ability of patients to pay for our products.

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, such studies have resulted, and may in the future result, in the discontinuation or variation of product marketing authorizations or

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requirements for risk management programs, such as a patient registry. Any of these events could adversely affect our profitability, business, financial condition, results of operations, cash flows, and/or ordinary share price.

THE DEVELOPMENT, APPROVAL PROCESS, MANUFACTURE AND COMMERCIALIZATION OF BIOSIMILAR PRODUCTS INVOLVE UNIQUE CHALLENGES AND UNCERTAINTIES, 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 reference biological product, and for which there are no clinically meaningful differences between the biosimilar and the reference biological product in terms of safety, purity and potency. Although the Biologics Price Competition and Innovation Act of 2009 established a framework for the review and approval of biosimilar products and the FDA has begun to review and approve biosimilar product applications, there continues to be significant uncertainty regarding the regulatory pathway in the U.S. and in other countries to obtain approval for biosimilar products. There is also uncertainty regarding the commercial pathway to successfully market and sell such products.

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 biosimilar product for many years. If we are unable to obtain FDA or other non-U.S. regulatory authority approval for our products, we will be unable to market them. Even if our biosimilar products are approved for marketing, the 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 effective yet offer a more competitive price or other benefit over existing therapies. In addition, the development and manufacture of biosimilars pose unique challenges 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. 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 ordinary 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 ordinary 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 ordinary share price.

THE ILLEGAL DISTRIBUTION AND SALE BY THIRD PARTIES OF COUNTERFEIT VERSIONS OF OUR PRODUCTS OR OF DIVERTED OR 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

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attributed to the authentic product. In addition, unauthorized diversions of products or 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, diversion, or theft could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary 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% in certain jurisdictions, including the U.S. Moreover, because of the discount pricing typically involved with bioequivalent (generic) products, patented branded products generally realize a 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 ordinary share price.

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 and branded businesses, depends in part on our or any partner's or supplier's ability to obtain, maintain and enforce patents, and protect trademarks, trade secrets, know-how, and other intellectual property and 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 and trademarks of sufficient scope to lawfully prevent third-parties from developing and/or marketing infringing products. In the absence of intellectual property or other protection, competitors may adversely affect our branded products business by independently developing and/or 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

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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. In addition, branded products often have market viability based upon the goodwill of the product name, which typically benefits from trademark protection. Our branded products may therefore also be subject to risks related to the loss of trademark or patent protection or to competition from generic or other branded products. Challenges can come from other businesses or governments, and governments could require compulsory licensing of this intellectual property. Any challenge to, or invalidation or circumvention of, our intellectual property (including patents or patent applications and trademark protection) 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 ordinary 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 ordinary 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 ordinary share price.

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We also face increasing competition from lower-cost generic products and other branded products. Certain of our products are not protected by patent rights or have limited patent life and will soon lose patent protection. Loss of patent protection for a product typically is followed promptly by generic substitutes. As a result, sales of many of these products may decline or stop growing over time. Various factors may result in the sales of certain of our products, particularly those acquired in the EPD Transaction, declining faster than has been projected, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. In addition, legislative proposals emerge from time to time in various jurisdictions to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could increase competition and worsen this negative effect on our sales and, potentially, our business, financial condition, results of operations, cash flows and/or ordinary share price.

Competitors' products may also be safer, more effective, more effectively marketed or sold, or have lower prices or better performance features than ours. We cannot predict with certainty the timing or impact of competitors' products. In addition, our sales may suffer as a result of changes in consumer demand for our products, including those related to fluctuations in consumer buying patterns tied to seasonality or the introduction of new products by competitors, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary 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, 2015 and 2014, Mylan's top ten products in terms of sales, in the aggregate, represented approximately 29% and 33%, respectively, of its 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 ordinary share price could be materially adversely affected.

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

A significant portion of our revenues are 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 ordinary share price could be materially adversely affected.

During the years ended December 31, 2015, 2014 and 2013, Mylan's consolidated third party net sales to Cardinal Health, Inc. were approximately 12%, 12% and 15%, respectively; Mylan's consolidated third party net sales to McKesson Corporation were approximately 15%, 19% and 14%, respectively; and Mylan's consolidated third party net sales to AmeriSourceBergen Corporation were approximately 16%, 13% and 10%, respectively, of consolidated third party net sales.

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 ordinary share price.

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

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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 increases the negotiating power of these groups, potentially enabling them to attempt to extract price discounts, rebates, and other restrictive pricing terms on our products. The occurrence of any of the above risks could have a material adverse affect on our business, financial condition, results of operations, cash flows, and/or ordinary 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 ordinary 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, or at their manufacturing facilities, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary 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 controlled substances 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 similar regulatory agencies for procurement quotas in order to obtain these substances. Any delay or refusal by the DEA or such similar 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 ordinary share price.

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

All API imported into the EU has needed to be certified as complying with the good manufacturing practice standards established by the EU laws and guidance, as stipulated by the International Conference for Harmonization. These 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 the above risks could have a material adverse effect on

our business, financial condition, results of operations, cash flows, and/or ordinary share price.

WE HAVE A LIMITED NUMBER OF MANUFACTURING FACILITIES AND CERTAIN THIRD PARTY SUPPLIERS PRODUCING A SUBSTANTIAL PORTION OF OUR PRODUCTS, SOME OF WHICH REQUIRE A HIGHLY EXACTING AND COMPLEX MANUFACTURING PROCESS.

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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, other regulatory action, 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 ordinary share price.

In addition, the manufacture of some of our products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including among others equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, natural disasters, power outages, labor unrest, and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause, and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. If we or one of our suppliers experiences significant manufacturing problems, such problems could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTHCARE 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 healthcare 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.

Pharmaceutical manufacturers that participate in the Medicaid Drug Rebate Program, such as Mylan, are required to report certain pricing data to the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers the Medicare and Medicaid programs. This data includes the Average Manufacturer Price ("AMP") for each of the manufacturer's covered outpatient drugs. CMS calculates a type of U.S. federal ceiling on reimbursement rates to pharmacies for multiple source drugs under the Medicaid program, known as the federal upper limit ("FUL"). The PPACA includes a provision requiring CMS to use the weighted average AMP for pharmaceutically and therapeutically equivalent multiple source drugs to calculate FULs, instead of the other pricing data CMS previously used. The provision was effective October 1, 2010; however, AMP-based FULs have not yet been implemented to set the federal ceiling on reimbursement rates for multiple source drugs. On January 21, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Health Reform Laws, including AMP-based FULs. These regulations generally become effective April 1, 2016. Although weighted average AMP-based FULs would not reveal Mylan's individual AMP, publishing a weighted average AMP available to customers and the public at large could negatively affect our commercial price negotiations.

In addition, 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, and we may be named as a defendant in 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 us 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 healthcare 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 or pursue civil and/or criminal sanctions. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may

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have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS or the U.S. Department of Veterans Affairs to be incomplete or incorrect. 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 ordinary 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 healthcare, and legislative healthcare 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 ordinary 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 ordinary 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 U.S. federal, U.S. state or other countries' laws and regulations may influence the prices of drugs and, therefore, could adversely affect the payment 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 payment rates are set and/or the way Medicaid rebates are calculated, could adversely affect the payment we receive for our products and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary 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 ordinary share price.

HEALTHCARE 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, healthcare services in the U.S., and it is likely that Congress and state legislatures and health agencies will continue to focus on healthcare reform in the future. The PPACA and The Health

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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 healthcare 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, cash flows, and/or ordinary share price.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides healthcare at low cost to consumers and regulates pharmaceutical prices, patient eligibility and/or reimbursement levels to control costs for the government-sponsored healthcare 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. healthcare system, or to the healthcare 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 ordinary 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, marketing, and pricing 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 EU. 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 ordinary 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 ordinary 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 ordinary 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

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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 ordinary share price.

WE 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 SUBSTANTIAL INDEBTEDNESS COULD LEAD TO ADVERSE CONSEQUENCES.

Our 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 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 do not have sufficient cash flow to service our indebtedness, we 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 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 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 ordinary 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, 2014 Term Loan, 2015 Term Loan, 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

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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 ordinary 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 commercial, 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 ordinary share price could be materially adversely affected.

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 ordinary 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 ordinary 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 our 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 EPD Transaction, which might adversely affect our ability to

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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 ordinary share price.

OUR ACTUAL FINANCIAL POSITION AND RESULTS OF OPERATIONS MAY DIFFER MATERIALLY FROM THE UNAUDITED PRO FORMA FINANCIAL INFORMATION INCLUDED IN THIS ANNUAL REPORT.

The unaudited pro forma financial information contained in the Form 10-K may not be an indication of what our financial position or results of operations would have been had the EPD Transaction been completed on the date indicated nor are they indicative of the future operating results of Mylan N.V. The unaudited pro forma financial information has been derived from the historical consolidated financial statements of Mylan N.V., Mylan Inc., and the combined financial statements of the EPD Business and reflect certain adjustments related to past operating performance and acquisition accounting adjustments, such as increased amortization expense based on the fair value of assets acquired, the impact of transaction costs, and the related income tax effects. The information upon which these adjustments have been made is subjective, and these types of adjustments are difficult to make with complete accuracy. Accordingly, the actual financial position and results of our operations following the EPD Transaction may not be consistent with, or evident from, this unaudited pro forma financial information and other factors may affect our business, financial condition, results of operations, cash flows, and/or ordinary share price, including, among others, those described herein.

THE EPD BUSINESS HAS A LIMITED HISTORY IN THE STRUCTURE IN WHICH IT CURRENTLY OPERATES.

Prior to the consummation of the EPD Transaction, the EPD Business had been operated by Abbott as part of its broader corporate organization. As a result of the EPD Business's separation from Abbott, the EPD Business may encounter operational or financial difficulties that would not have occurred if the EPD Business continued operating in its former structure. For example, the EPD Business's working capital and capital for general corporate purposes have historically been provided as part of the corporate-wide cash management policies of Abbott. We may need to obtain additional financing for the EPD Business from lenders, public offerings or private placements of debt or equity securities, strategic relationships, or other arrangements. Similarly, the EPD Business's combined financial statements reflect allocations of expenses from Abbott for corporate functions and may differ from the expenses the EPD Business would have incurred had the EPD Business been operated by us, and the EPD Business will need to make significant investments to replicate or outsource from other providers certain facilities, systems, infrastructure, and personnel to which it will no longer have access after closing and, for certain services to be provided pursuant to a transition services agreement entered into in connection with the consummation of the EPD Transaction (the "Transition Services Agreement"), the expiration of the Transition Services Agreement. In addition, as a result of the separation of the EPD Business from Abbott, other significant changes may occur in the EPD Business's cost structure, management, financing, and business operations as a result of operating separately from Abbott that could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

THE EPD BUSINESS AND ABBOTT ARE INTERDEPENDENT WITH RESPECT TO CERTAIN TRANSITION SERVICES AND MANUFACTURING AND SUPPLY OF CERTAIN PRODUCTS AND SHARE CERTAIN INTELLECTUAL PROPERTY.

Prior to the EPD Transaction, Abbott or one of its affiliates performed various corporate functions for the EPD Business, such as accounting, information technology, and finance, among others. Abbott is required to provide some of these functions to the EPD Business for a period of time pursuant to the Transition Services Agreement. The EPD Business may incur temporary interruptions in business operations if it cannot complete the transition effectively from Abbott's existing operational systems and the transition services that support these functions as the EPD Business replaces these systems or integrates them with our systems. The EPD Business is dependent on Abbott providing certain transition services, and we could be negatively impacted if Abbott fails to perform under the Transition Services Agreement. In addition, Abbott or one of its affiliates is required to manufacture products for the EPD

Business, pursuant to certain agreements providing for, among other things, manufacturing and supply services. Disruptions or disagreements related to the third-party manufacturing relationship with Abbott could impair our ability to ship products to the market on a timely basis and could, among other consequences, subject us to exposure to claims from customers.

Mylan has certain obligations to provide transition services to Abbott and to manufacture for and supply products to Abbott. Accordingly, we may need to allocate resources to provide transition services or manufacturing capacity to Abbott in lieu of supplying products for the EPD Business, which could have a negative impact on us.

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In addition, Abbott or one of its affiliates owns registrations, including marketing authorizations, for certain products of the EPD Business in certain jurisdictions, and disagreements could arise regarding Abbott's or our use of such registrations in the territory allocated to each party.

The risks related to the foregoing relationships between us and Abbott could be exacerbated if Abbott fails to perform under the agreements between Mylan and Abbott or the EPD Business fails to have necessary systems and services in place when the obligations under the agreements between Mylan and Abbott expire, and such risks could have a negative impact on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

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

Parties with which we currently do business or may do business in the future, including customers and suppliers, may experience ongoing uncertainty associated with the EPD 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 EPD 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 ordinary share price.

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

We are enhancing and further developing our global 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 ordinary 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 (including trade secrets or other intellectual property, proprietary business information and personal 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 technology 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 state and quasi-state actors, criminal groups, "hackers" and others. Maintaining the security, confidentiality and integrity of this confidential information (including trade secrets or other intellectual property, proprietary, business information and personal

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, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential 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,

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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, or loss, misappropriation, and/or unauthorized access, use or disclosure of confidential information, including personal information regarding our patients and employees, 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 ordinary 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 or the improper dissemination of material non-public 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 ordinary share price.

Risks Related to the Offer

THE OFFER MAY NOT BE COMPLETED ON FAVORABLE TERMS OR AT ALL, AND IF COMPLETED, THE OFFER MAY NOT ACHIEVE THE INTENDED BENEFITS OR MAY DISRUPT OUR PLANS AND OPERATIONS.

Our obligation to complete the public offer to the shareholders of Meda AB (publ.) (“Meda”) to acquire all of the outstanding shares of Meda (the “Offer”) is subject to the satisfaction or waiver of a number of customary closing conditions, including (i) holders of at least 90% of the outstanding Meda shares tendering their shares into the Offer and (ii) receipt of all necessary regulatory, governmental or similar clearances, approvals and decisions, including from competition authorities. Since the fulfillment of these conditions is beyond our control, there are no guarantees as to when the Offer will be completed, or that it will be completed at all. Uncertainty in the financial markets regarding if or when the Offer will be completed may negatively affect the price of our ordinary shares. In addition, to grant such clearances, approvals, and decisions, competition authorities may impose requirements, limitations, or costs on the conduct of our businesses or require divestitures after completion of the Offer that could delay the completion of the Offer or may reduce the anticipated benefits of the Offer.

If the proposed acquisition of Meda is not completed for any reason, we would be subject to a number of risks, including, among others:

- incurring substantial expenses and costs, including legal, accounting, financing, and advisory fees, that we would be unable to recover; and
- negative reactions from the financial markets or from our customers, vendors, and employees.

If the Offer is completed, we cannot assure you that we will be able to successfully integrate the business of Meda with the business of Mylan or otherwise realize the expected benefits of the Offer. Mylan’s ability to realize the anticipated benefits of the Offer will depend, to a large extent, on Mylan’s ability to integrate Meda with the business of Mylan and realize the expected benefits of the combined business. The combination of two independent businesses is a complex, costly, and time-consuming process. The integration will require significant time and focus from management following the Offer and may divert attention from the day-to-day operations of the combined business. Integration challenges, many of which are outside of Mylan’s control, may prevent the expected synergies and operating efficiencies of the Offer from being fully realized, which could result in higher than anticipated costs for the combined company. Additionally, consummation of the Offer could disrupt current plans and operations and delay the achievement of our strategic objectives. Failing to achieve the expected synergies and operating efficiencies of the Offer or any delay in the achievement of our strategic objectives could have a material adverse effect on Mylan’s business, financial condition, results of operations, cash flows, and/or ordinary share price.

Even if the operations of Mylan and Meda are integrated successfully, the full anticipated benefits of the Offer, including the synergies, operating efficiencies, or sales or growth opportunities may not be achieved within the

anticipated time frame or at all. Mylan has entered into a new bridge loan credit facility under which it may obtain loans in an aggregate amount up to $10.05 billion to finance the cash portion of the consideration for the Offer and/or repay certain existing indebtedness. Mylan's business may be negatively impacted if it is unable to effectively manage its expanded operations and increased level of indebtedness following the Offer. Mylan's increased indebtedness following the consummation of the Offer could also have adverse consequences, including but not limited to (i) increasing our vulnerability to general adverse economic and industry

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conditions and (ii) limiting our flexibility in planning for or reacting to challenges, opportunities, and changes in our businesses and the markets in which we operate. All of these factors could cause dilution to the earnings per share of the combined business, decrease or delay any potential accretive effect of the Offer, and/or have a material adverse effect on Mylan's business, financial condition, results of operations, cash flows, and/or ordinary 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 16 Contingencies, in the accompanying Notes to Consolidated Financial Statements in this Annual Report.

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PART II

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

On February 27, 2015, Mylan Inc. became an indirect wholly owned subsidiary of Mylan N.V., and Mylan Inc.'s common stock ceased trading on the NASDAQ Global Select Stock Market ("NASDAQ"). Mylan N.V.'s ordinary shares began trading on NASDAQ under the symbol "MYL" on March 2, 2015. On November 4, 2015, Mylan N.V.'s ordinary shares began trading on the Tel Aviv Stock Exchange (the "TASE") under the symbol "MYL."

The following table sets forth the quarterly high and low sales prices for Mylan N.V.'s ordinary shares for the quarterly periods of 2015 after March 31, 2015; for Mylan N.V.'s ordinary shares (from March 2, 2015 through March 31, 2015) and Mylan Inc.'s common stock (from January 1, 2015 through February 27, 2015) for the quarterly period ended March 31, 2015; and Mylan Inc.'s common stock for the quarterly periods of 2014, each as reported on NASDAQ:

Year Ended December 31, 2015	High	Low
Three months ended March 31, 2015	$65.63	$52.21
Three months ended June 30, 2015	76.69	57.46
Three months ended September 30, 2015	73.91	39.16
Three months ended December 31, 2015	55.51	37.59
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

As of December 10, 2015, there were approximately 185,000 holders of Mylan N.V. ordinary shares, including those held in street or nominee name.

The Company did not pay dividends in 2015 and does not intend to pay dividends on its ordinary shares in the near future.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased[1][2]	Average Price Paid per Share[3]	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 - October 30, 2015	—	$—	—	$—
November 1 - November 30, 2015	918,332	$51.34	918,332	$952,871,202
December 1 - December 31, 2015[4]	392,861	$58.32	392,861	$929,959,112
Total	1,311,193	$51.46	1,311,193	$929,959,112

(1)On November 16, 2015, the Company announced that its Board of Directors had approved the repurchase of up to $1 billion of the Company's ordinary shares either in the open market through privately-negotiated transactions or in one or more self tender offers (the "Share Repurchase Program"). The Share Repurchase Program does not obligate the Company to acquire any particular amount of ordinary shares and expires on August 27, 2016.

(2)The number of shares purchased is based on the purchase date and not the settlement date.

(3)Average price per share includes commissions.

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(4)At December 31, 2015, the Share Repurchase Program has approximately $930 million that can be repurchased.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In the past three years, we have issued unregistered securities in connection with the following transactions:
In December 2015, Mylan N.V. issued $1.0 billion aggregate principal amount of Senior Notes, comprised of 3.000% Senior Notes due 2018 and 3.750% Senior Notes due 2020. 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 Regulations S under the Securities Act.

In June 2013, Mylan Inc. 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. Mylan Inc. 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.

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, 2011, 2012, 2013, 2014 and 2015 of $100 invested on December 31, 2010 in the Company's Ordinary Shares, the Standard & Poor's 500 Index and the Dow Jones U.S. Pharmaceuticals Index.

	12/10	12/11	12/12	12/13	12/14	12/15
Mylan N.V. [1]	100.00	101.56	129.91	205.40	266.78	255.89
S&P 500	100.00	102.11	118.45	156.82	178.29	180.75
Dow Jones U.S. Pharmaceuticals	100.00	118.64	135.14	180.98	219.72	233.36

[1] Mylan Inc. prior to February 27, 2015.

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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" included in Item 7 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.

Mylan N.V. is the successor to Mylan Inc., the information set forth below refers to Mylan Inc. for periods prior to February 27, 2015, and to Mylan N.V. on and after February 27, 2015.

	Year Ended December 31,				
(In millions, except per share amounts)	2015	2014	2013	2012	2011[1]
Statements of Operations:					
Total revenues	$9,429.3	$7,719.6	$6,909.1	$6,796.1	$6,129.8
Cost of sales [2]	5,213.2	4,191.6	3,868.8	3,887.8	3,566.4
Gross profit	4,216.1	3,528.0	3,040.3	2,908.3	2,563.4
Operating expenses:					
Research and development	671.9	581.8	507.8	401.3	294.7
Selling, general and administrative	2,180.7	1,625.7	1,408.5	1,392.4	1,214.6
Litigation settlements, net	(97.4)	47.9	(14.6)	(3.1)	48.6
Other operating (income) expense, net	—	(80.0)	3.1	8.3	—
Earnings from operations	1,460.9	1,352.6	1,135.5	1,109.4	1,005.5
Interest expense	339.4	333.2	313.3	308.7	335.9
Other expense (income), net	206.1	44.9	74.9	(3.5)	15.0
Earnings before income taxes and noncontrolling interest	915.4	974.5	747.3	804.2	654.6
Income tax provision	67.7	41.4	120.8	161.2	115.8
Net earnings attributable to the noncontrolling interest	(0.1)	(3.7)	(2.8)	(2.1)	(2.0)
Net earnings attributable to Mylan N.V. ordinary shareholders	$847.6	$929.4	$623.7	$640.9	$536.8
Selected Balance Sheet data:					
Total assets[3] [4]	$22,267.7	$15,820.5	$15,086.6	$11,847.8	$11,530.5
Working capital[3] [4] [5]	2,350.5	1,137.2	1,258.6	1,485.4	804.5
Short-term borrowings	1.3	330.7	439.8	299.0	128.1
Long-term debt, including current portion of long-term debt[3]	7,294.3	8,104.1	7,543.8	5,395.6	5,130.9
Total equity	9,765.8	3,276.0	2,959.9	3,355.8	3,504.8
Earnings per ordinary share attributable to Mylan N.V. ordinary shareholders:					
Basic	$1.80	$2.49	$1.63	$1.54	$1.25
Diluted	$1.70	$2.34	$1.58	$1.52	$1.22
Weighted average ordinary shares outstanding:					
Basic	472.2	373.7	383.3	415.2	430.8
Diluted	497.4	398.0	394.5	420.2	438.8

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(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: $854.2 million, $375.9 million, $351.1 million, $349.5 million and $348.6 million for the years ended December 31, 2015, 2014, 2013, 2012 and 2011, respectively. In addition, cost of sales included the following amounts related to impairment charges to intangible assets: $31.3 million, $27.7 million, $18.0 million, $41.6 million and $16.2 million for the years ended December 31, 2015, 2014, 2013, 2012 and 2011, respectively.
(3)Pursuant to the Company's early adoption of ASU 2015-03, Interest - Imputation of Interest, as of December 31, 2015, as further described in Item 8. Note 2 Summary of Significant Accounting Policies, deferred financing fees related to term debt has been retrospectively reclassified from other assets to long-term debt or the current portion of long-term debt, depending on the debt instrument, on the Consolidated Balance Sheets for all periods presented. The Company retrospectively reclassified approximately $34.4 million, $42.7 million, $36.3 million and $37.3 million for the years ended December 31, 2014, 2013, 2012 and 2011, respectively.
(4)Pursuant to the Company's early adoption of ASU 2015-17, Balance Sheet Classification of Deferred Taxes, as of December 31, 2015, as further described in Item 8. Note 2 Summary of Significant Accounting Policies, deferred tax assets and liabilities that had been previously classified as current have been retrospectively reclassified to noncurrent on the Consolidated Balance Sheets for all periods presented. The reclassification resulted in a decrease in current assets of approximately $345.7 million, $250.1 million, $229.3 million and $202.9 million for the years ended December 31, 2014, 2013, 2012 and 2011, respectively. The reclassification resulted in a decrease in current liabilities of approximately $0.2 million, $1.5 million, $1.3 million and $1.2 million for the years ended December 31, 2014, 2013, 2012 and 2011, respectively.
(5)Working capital is calculated as current assets minus current liabilities.

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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 N.V. and subsidiaries for the periods presented. Unless context requires otherwise, the "Company," "Mylan," "our," or "we" refer to Mylan N.V. and its subsidiaries. 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 (the "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 proposed acquisition of Meda AB (publ.) ("Meda") by Mylan (the "Proposed Transaction"), Mylan's related public offer to the shareholders of Meda to acquire all of the outstanding shares of Meda (the "Offer"), Mylan's acquisition (the "EPD Transaction") of Mylan Inc. and Abbott Laboratories' ("Abbott") non-U.S. developed markets specialty and branded generics business (the "EPD Business"), the benefits and synergies of the EPD Transaction and the Proposed Transaction, future opportunities for Mylan, Meda, or the combined company and products, and any other statements regarding Mylan's, Meda's, or the combined company'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," "continue," "target" and variations of these words or 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: uncertainties related to the Proposed Transaction, including as to the timing of the Proposed Transaction, uncertainties as to whether Mylan will be able to complete the Proposed Transaction, the possibility that competing offers will be made, the possibility that certain conditions to the completion of the Offer will not be satisfied, and the possibility that Mylan will be unable to obtain regulatory approvals for the Proposed Transaction or be required, as a condition to obtaining regulatory approvals, to accept conditions that could reduce the anticipated benefits of the Proposed Transaction; the ability to meet expectations regarding the accounting and tax treatments of the EPD Transaction and the Proposed 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 EPD Business and Meda 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 EPD Transaction and the Proposed Transaction; the retention of certain key employees of the EPD Business and Meda being difficult; the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with the EPD Transaction and the Proposed Transaction within the expected time-frames or at all and to successfully integrate the EPD Business and Meda; 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 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"); any regulatory, legal, or other impediments to Mylan's ability to bring new products to market; success of clinical trials and Mylan's ability to execute on new product opportunities; any changes in or difficulties with our inventory of, and our ability to manufacture and distribute, the EpiPen® Auto-Injector to meet anticipated demand; 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 impact of competition; changes in the economic and financial conditions of the businesses of Mylan, Meda, or the combined company; 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 accounting principles generally accepted in the United States of America ("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, 2015 and our other filings with the SEC. These risks and uncertainties also include those risks and uncertainties that will be discussed in the offer document to be filed with the Swedish Financial Supervisory Authority ("SFSA"), the Registration Statement on Form S-4 to be filed with the SEC and the EU Prospectus to be filed with the Netherlands Authority for the Financial Markets ("AFM") or another competent EU authority. You can access Mylan's filings with the SEC through the SEC website at www.sec.gov, and Mylan strongly encourages you to do so. Mylan undertakes no obligation to update any statements herein for revisions or changes after the filing date of this Form 10-K.

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ADDITIONAL INFORMATION

In connection with the Offer, an offer document will be filed with the SFSA and published by Mylan upon approval by the SFSA. In addition, Mylan expects to file certain materials with the SEC, including, among other materials, a Registration Statement on Form S-4. Mylan also expects to file an EU Prospectus with the AFM or another competent EU authority. This report is not intended to be, and is not, a substitute for such documents or for any other document that Mylan may file with the SFSA, the SEC, the AFM or any other competent EU authority in connection with the Offer. INVESTORS AND SECURITYHOLDERS OF MEDA ARE URGED TO READ ANY DOCUMENTS FILED WITH THE SFSA, THE SEC AND THE AFM OR ANY OTHER COMPETENT EU AUTHORITY CAREFULLY AND IN THEIR ENTIRETY (IF AND WHEN THEY BECOME AVAILABLE) BEFORE MAKING AN INVESTMENT DECISION BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYLAN, MEDA AND THE OFFER. Such documents will be available free of charge through the website maintained by the SEC at www.sec.gov, on Mylan's website at medatransaction.mylan.com or, to the extent filed with the AFM, through the website maintained by the AFM at www.afm.nl, or by directing a request to Mylan at 724-514-1813 or investor.relations@mylan.com. Any materials filed by Mylan with the SFSA, the SEC, the AFM or any other competent EU authority that are required to be mailed to Meda shareholders will also be mailed to such shareholders.

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 healthcare by creating better health for a better world, and our mission is to provide the world’s 7 billion people access to high quality medicine. To do so, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership.

Mylan offers one of the industry’s broadest product portfolios, including more than 1,400 marketed products, to customers in approximately 165 countries and territories. We operate a global, high quality vertically-integrated manufacturing platform, which includes more than 50 manufacturing and research and development (“R&D”) facilities around the world and one of the world’s largest active pharmaceutical ingredient (“API”) operations. We also operate a strong 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 development 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:

EPD Business

On July 13, 2014, Mylan N.V., Mylan Inc., and Moon of PA Inc. entered into a definitive agreement with Abbott to acquire the EPD Business in an all-stock transaction. On November 4, 2014, Mylan N.V., Mylan Inc., and Moon of PA Inc. and Abbott entered into an amended and restated definitive agreement implementing the transaction (the “EPD Transaction Agreement”). The EPD Transaction closed on February 27, 2015 (the “EPD Transaction Closing Date”),

after receiving approval from Mylan Inc.'s shareholders on January 29, 2015. At closing, Abbott transferred the acquired EPD Business to Mylan N.V., in exchange for 110 million ordinary shares of Mylan N.V. Immediately after the transfer of the acquired EPD Business, Mylan Inc. merged with Moon of PA Inc., an indirect wholly owned subsidiary of Mylan N.V., with Mylan Inc. becoming an indirect wholly owned subsidiary of Mylan N.V. In addition, Mylan Inc.'s outstanding common stock was exchanged on a one to one basis for Mylan N.V. ordinary shares. As a result of the EPD Transaction, Mylan N.V.'s corporate seat is located in Amsterdam, the Netherlands, its principal executive offices are located in Hatfield, Hertfordshire, England and Mylan N.V. group's global headquarters are located in Canonsburg, Pennsylvania.

The acquired EPD 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

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acquisition, Mylan N.V. has significantly expanded and strengthened its product portfolio in Europe, Japan, Canada, Australia and New Zealand.

The purchase price for Mylan N.V. of the acquired EPD Business, which was on a debt-free basis, was $6.31 billion based on the closing price of Mylan Inc.'s stock as of the EPD Transaction Closing Date, as reported by NASDAQ. At the closing of the EPD Transaction, former shareholders of Mylan Inc. owned approximately 78% of Mylan N.V.'s ordinary shares and certain affiliates of Abbott (the "Abbott Shareholders") owned approximately 22% of Mylan N.V.'s ordinary shares. On the EPD Transaction Closing Date, Mylan N.V., Abbott and Abbott Shareholders entered into a shareholder agreement (the "Shareholder Agreement"). Following an underwritten public offering of Abbott Shareholders of a portion of Mylan N.V.'s ordinary shares held by them, which offering closed on April 6, 2015, the Abbott Shareholders collectively owned approximately 14.2% of Mylan N.V.'s outstanding ordinary shares.

In accordance with U.S. GAAP, Mylan N.V. used the purchase method of accounting to account for the EPD Transaction with Mylan Inc. being treated as the accounting acquirer. Under the purchase method of accounting, the assets acquired and liabilities assumed in the EPD Transaction were recorded at their respective estimated fair values at the EPD Transaction Closing Date.

Jai Pharma Limited

On February 2, 2015, the Company signed a definitive agreement to acquire certain female healthcare businesses from Famy Care Limited (such business "Jai Pharma Limited"), a specialty women's healthcare company with global leadership in generic oral contraceptive products. On November 20, 2015, the Company completed the acquisition of Jai Pharma Limited through its wholly owned subsidiary Mylan Laboratories Limited for a cash payment of $750 million plus additional contingent payments of up to $50 million for the filing for approval with, and receipt of approval from, the U.S. Food and Drug Administration ("FDA") of a product under development with Jai Pharma Limited.

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

Other Transactions

On January 8, 2016, the Company entered into an agreement with Momenta Pharmaceuticals, Inc. ("Momenta") to develop, manufacture and commercialize up to six of Momenta's current biosimilar candidates, including Momenta's biosimilar candidate, ORENCIA® (abatacept). Mylan paid an up-front cash payment of $45 million to Momenta. Under the terms of the agreement, Momenta is eligible to receive additional contingent milestone payments of up to $200 million. The Company and Momenta will jointly be responsible for product development and will equally share in the costs and profits of the products. Under the agreement, Mylan will lead the worldwide commercialization efforts.

In December 2015, the Company entered into an agreement to acquire certain European intellectual property rights and marketing authorizations. The purchase price was $202.5 million including approximately $2.5 million of transaction costs. The Company accounted for this transaction as an asset acquisition. The Company paid $10 million at the closing of the transaction and expects to pay approximately $165 million during 2016 and the remaining $25 million during the first quarter of 2017, subject to certain timing conditions. The asset will be amortized over a useful life of 5 years.

On November 16, 2015, the Company announced that its Board of Directors had approved the Share Repurchase Program. The Share Repurchase Program does not obligate the Company to acquire any particular amount of ordinary shares. The authorization expires on August 27, 2016.

On November 13, 2015, the Company announced that the acceptance condition to our previously announced offer (the "Perrigo Offer") to acquire all of the issued and outstanding ordinary shares of Perrigo Company plc ("Perrigo") had not been satisfied and the Perrigo Offer had lapsed in accordance with its terms. Any Perrigo ordinary shares that were tendered by Perrigo shareholders were returned to the respective Perrigo shareholders.

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During 2015, the Company entered into agreements with multiple counterparties to acquire certain marketed pharmaceutical products for upfront payments totaling approximately $360.8 million, which was paid during the year ended December 31, 2015 and is included in investing activities in the Consolidated Statements of Cash Flows. The Company will be subject to potential future sales and other contingent milestone payments under the terms of one of the agreements.

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 FDA approval, commercialization of Revefenacin (“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 the reimbursement of Theravance Biopharma's development 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. On September 14, 2015, Mylan announced the initiation of the Phase 3 program that will support the registrational development program of TD-4208 in the U.S. In addition to funding the U.S. registrational development program, the Company made a $30 million investment in Theravance Biopharma’s common stock during the first quarter of 2015, which is being accounted for as an available-for-sale security. The Company incurred $15 million in upfront development costs during the year ended December 31, 2015. 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, which was held in escrow, was released during the year ended December 31, 2015 upon the satisfaction of certain conditions.

Senior Credit Facilities and Issuance of Senior Notes

In December 2015, the Company issued $1.0 billion aggregate principal amount of Senior Notes, comprised of 3.000% Senior Notes due 2018 and 3.750% Senior Notes due 2020 (the “December 2015 Senior Notes”). The net proceeds from the offering were used to repay amounts outstanding under the Revolving Facility and the Accounts Receivable Securitization Facility (the “Receivables Facility”) and to finance a portion of the Share Repurchase Program.

On July 15, 2015, the Company entered into a term credit agreement (the “2015 Term Credit Agreement”) among the Company, as guarantor, Mylan Inc. (the “Borrower”), certain lenders and PNC Bank, National Association as the administrative agent. The 2015 Term Credit Agreement provided for a delayed-draw term loan credit facility under which the Borrower obtained loans in the aggregate amount of $1.6 billion, consisting of (i) a closing date term loan (the “Closing Date Loan”) in the amount of $1.0 billion, borrowed on July 15, 2015, which was used to redeem the Company’s 7.875% Senior Notes due 2020 and (ii) a delayed draw term loan (the “Delayed Draw Loan,” and together with the Closing Date Loan, the “2015 Term Loans”) in the amount of $600.0 million, borrowed on September 15, 2015, which was primarily used to repay the notional amount of the Company’s 3.750% Cash Convertible Notes due 2015 (the “Cash Convertible Notes”) that matured on September 15, 2015.

In December 2014, the Company entered into a revolving credit agreement with a syndication of lenders, which contains a $1.5 billion revolving facility (the “Revolving Facility”). The 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 Revolving Facility become due and payable on December 19, 2019. On June 19, 2015, the Company entered into an additional amendment to the Revolving Credit Agreement (the “Incremental Amendment”). The

Incremental Amendment provides that ING Bank N.V. will make available $150 million of additional revolving commitments under the Revolving Facility (the “Increased Commitments”), increasing the aggregate principal amount of the revolving commitments available under the Revolving Facility from $1.5 billion to $1.65 billion. Proceeds from the Increased Commitments will be used for working capital, capital expenditures and other lawful corporate purposes.

Financial Summary

For the year ended December 31, 2015, Mylan reported total revenues of $9.43 billion compared to $7.72 billion for the year ended December 31, 2014. This represents an increase in revenues of $1.71 billion, or 22.1%. Consolidated gross

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profit for the current year was $4.22 billion, compared to $3.53 billion in the prior year, an increase of $688.1 million, or 19.5%. For the current year, earnings from operations were $1.46 billion, as compared to $1.35 billion for the year ended December 31, 2014, an increase of $108.3 million, or 8.0%.

Net earnings attributable to Mylan N.V. ordinary shareholders decreased $81.8 million, or 8.8%, to $847.6 million for the year ended December 31, 2015 compared to $929.4 million for the prior year. Diluted earnings per ordinary share attributable to Mylan N.V. decreased 27.4% from $2.34 to $1.70 for the year ended December 31, 2015 compared to the prior year primarily due to the impact of ordinary shares issued in the current year for the acquisition of the EPD Business and additional related costs, including amortization, partially offset by the additional earnings from the acquired EPD Business. In the prior year we recorded a gain related to the resolution of contingent consideration related to the Agila transaction and tax benefits related to the merger of the Company's wholly owned subsidiaries, Agila Specialties Private Limited and Onco Therapies Limited, into Mylan Laboratories Limited.

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" third party net sales and total revenues. 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, 2015, 2014 and 2013.

	Year Ended December 31,			2015 Percent Change		2014 Percent Change	
(In millions, except percentage)	2015	2014	2013	Actual	Constant Currency	Actual	Constant Currency
Generics:							
Third party net sales							
North America	$3,895.6	$3,361.2	$3,006.6	16 %	16 %	12 %	12 %
Europe[(a)]	2,205.6	1,476.8	1,429.7	49 %	65 %	3 %	3 %
Rest of World	2,056.6	1,621.3	1,438.6	27 %	38 %	13 %	18 %
Total third party net sales[(a)]	8,157.8	6,459.3	5,874.9	26 %	33 %	10 %	11 %
Other third party revenues	40.8	51.1	25.8				
Total third party revenues	8,198.6	6,510.4	5,900.7				
Intersegment sales	6.3	4.7	5.7				
Generics total revenues	8,204.9						