MYLAN INC.
Form 10-K
February 28, 2013

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, 2012

OR

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

Commission file number 1-9114

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

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

1500 Corporate Drive, Canonsburg, Pennsylvania 15317
(Address of principal executive offices)
(724) 514-1800
(Registrant's telephone number, including area code)

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

Title of Each Class:	Name of Each Exchange on Which Registered:
Common Stock, par value $0.50 per share	The NASDAQ Stock Market

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

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

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

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

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

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

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

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

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

The aggregate market value of the outstanding common stock, other than shares held by persons who may be deemed affiliates of the registrant, as of June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $8,624,667,439.

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

INCORPORATED BY REFERENCE

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

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For the Year Ended December 31, 2012

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PART I

ITEM 1. Business

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

Overview

Throughout its history, Mylan has been recognized as a leader in the United States ("U.S.") generic pharmaceutical market. Since 2007, Mylan has transformed itself and today is one of the largest generic and specialty pharmaceuticals companies in the world in terms of revenue. This transformation has taken place through organic growth and external expansion. Our leadership position in the U.S. generic pharmaceutical industry is the result of our ability to obtain Abbreviated New Drug Application ("ANDA") approvals, as well as our reliable and high quality supply chain. Through the acquisitions of Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited), Merck KGaA's generics and specialty pharmaceutical business (the "former Merck Generics business"), Bioniche Pharma Holdings Limited ("Bioniche Pharma") and Pfizer Inc.'s ("Pfizer's") respiratory delivery platform, we have created a horizontally and vertically integrated platform with global scale, augmented our diversified product portfolio and further expanded our range of capabilities, all of which we believe position us well for the future.

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

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

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

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

Our Operations

Mylan has two segments, "Generics" and "Specialty." Our revenues are primarily derived from the sale of generic and branded generic pharmaceuticals, specialty pharmaceuticals and API. Our generic pharmaceutical business is conducted primarily in the U.S. and Canada (collectively, "North America"); Europe, the Middle East, and Africa (collectively, "EMEA"); and India, Australia, Japan and New Zealand (collectively, "Asia Pacific"). Our API business is

conducted through Mylan Laboratories Limited ("Mylan India"), which is included within the Asia Pacific region in our Generics Segment. Our specialty pharmaceutical business is conducted by Mylan Specialty L.P. ("Mylan Specialty"). Refer to Note 13 to Consolidated Financial Statements included in Item 8 in this Form 10-K for additional information related to our segments.

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Generics Segment

North America

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

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

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

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

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

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

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EMEA

Our generic pharmaceutical sales in EMEA are generated primarily by our wholly owned subsidiaries in Europe, through which we have operations in 21 countries. The types of markets within Europe vary from country to country; however, when combined, the European market is the second largest generic pharmaceutical market in the world. Within Europe, by value, the generic prescription market in Germany is the largest, followed by France, the United Kingdom ("U.K."), Spain and Italy, respectively. Of the top ten generic prescription markets in Europe, we hold leadership positions in several company-branded markets, including the number one market share position in France, the number two market share position in Italy and a number three market share position in Belgium and Portugal.

The European generic prescription market varies significantly by country in terms of the extent of generic penetration, the key decision maker in terms of drug choice, and other important aspects. Some countries, including Germany, the U.K., the Netherlands and Poland, are characterized by relatively high generic penetration, ranging between 58% and 69% of total prescription market sales in the twelve months ended November 2012, based on volume. Conversely, other major European markets, including France, Italy and Spain, are characterized by much lower generic penetration, ranging between 17% and 33% of total prescription sales in the twelve months ended November 2012, based on volume. However, recent actions taken by governments, particularly in these latter southern European countries, to reduce health care costs could encourage further use of generic pharmaceutical products. In each of these under-penetrated markets, in addition to growth from new product launches, we expect our future growth to be driven by increased generic utilization and penetration.

The manner in which products are marketed also varies by country. In addition to selling pharmaceuticals under their International Nonproprietary Name ("INN") (i.e., active ingredient), 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.

Some countries, such as France and Italy, permit substitution by pharmacists. In other countries, such as the U.K., most prescriptions are written using the INN, which allows the pharmacist to dispense his or her preferred generic. However, if the prescription is written for the brand, then the brand must be dispensed.

France

In France, through our subsidiary Mylan S.A.S., we market a portfolio of approximately 305 products in an aggregate of approximately 645 dosage strengths. In France, we have the highest market share in the company-branded generic prescription 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.

Italy

In Italy, we market through our subsidiary Mylan S.p.A. a portfolio of approximately 175 products in an aggregate of approximately 345 dosage strengths. In Italy, we have the second highest market share in the company-branded generic prescription market. We believe that the Italian generic market is under-penetrated, with company-branded generics representing approximately 17% 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.

Spain

In Spain, we market through our subsidiary Mylan Pharmaceuticals S.L. a portfolio of approximately 110 products in an aggregate of approximately 300 dosage strengths. In Spain, we have the seventh highest market share in the

company-branded generic prescription market. The company-branded generic market comprised approximately 29% of the total Spanish pharmaceutical market by volume for the twelve months ended November 2012. We view further generic utilization and penetration of the Spanish market to be a key driver of our growth in that country.

Germany

In Germany, we market through our subsidiary Mylan dura a portfolio of approximately 160 products in an aggregate of approximately 360 dosage strengths. A tender system has been implemented in Germany and, as a result, health insurers play

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a major role in this market. Under a tender system, health insurers invite manufacturers to submit bids that establish prices for generic pharmaceuticals. Pricing pressures result from an effort to win the tender. As a result of these tenders, our business in Germany has declined, and future growth in the German marketplace will depend upon our ability to compete based primarily on price.

U.K.

In the U.K., we offer a broad product portfolio of approximately 190 products in an aggregate of approximately 405 dosage strengths. Mylan is ranked fourth in the U.K. generic prescription market, in terms of value, with an estimated market share of approximately 6%. Mylan is well positioned in the U.K. as a preferred supplier to wholesalers and is also focused on areas such as multiple retail pharmacies and hospitals. The U.K. generic prescription market is highly competitive, and any growth in the market will stem from new product launches, although we expect that the value will continue to be affected by price erosion.

Other EMEA Locations

We also have a notable presence in several other European company-branded generic prescription markets, including Belgium and Portugal, where we hold the third highest market share. We also operate in several other European markets, including the Netherlands, Sweden, Poland, Hungary, Slovakia, Slovenia and the Czech Republic. Additionally, we have an export business which is focused on Africa and the Middle East.

Our balanced geographical position, our leadership standing in many established and growing markets and our vertically integrated platform will all be keys to our future growth and success in EMEA.

Asia Pacific

We market generic pharmaceuticals in Asia Pacific through subsidiaries in Australia, Japan, New Zealand, India and Taiwan. Additionally, through Mylan India, we market API to third parties and supply other Mylan subsidiaries. We have the highest market share in both the Australian and New Zealand generic pharmaceuticals markets.

India

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

In addition to the sale of FDF products, Asia Pacific revenues are augmented by API sales. We currently have more than 250 APIs in the market or under development, and we focus our marketing efforts on regulated markets such as the U.S. and the European Union (the "EU"). We produce API for use in the manufacture of our own pharmaceutical products, as well as for use by third parties, in a wide range of categories, including anti-bacterials, central nervous system agents, anti-histamine/anti-asthmatics, cardiovasculars, anti-virals, anti-diabetics, anti-fungals, proton pump inhibitors and pain management drugs.

Mylan India has nine API and intermediate manufacturing facilities and two FDF facilities. All but one of these facilities are located in India, with one in China. Seven of the API facilities and two FDF facilities located in India are FDA approved, which makes Mylan India one of the largest companies in India in terms of FDA-approved API manufacturing capacity. From an API standpoint, growth is dependent upon us continuing to leverage our research and development capabilities to produce high quality, low cost API, while capitalizing on the greater API volumes

afforded through our vertically integrated platform.

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In August 2012, our subsidiary Mylan Pharmaceuticals Private Limited commenced commercial operations in India starting with the launch of a comprehensive portfolio of finished dosage form ARV products for the treatment of HIV/AIDS. We expect to enhance our commercial portfolio by adding products from additional therapeutic categories and to continue to build out our sales force across India to support this ongoing business expansion.

Australia

The generic pharmaceutical market in Australia had sales of approximately $1.4 billion during the twelve months ended August 2012. Through our wholly owned subsidiary Alphapharm, we have the highest market share in the off-patent market with an estimated 24% market share by volume in Australia, and we offer a portfolio of approximately 180 products in an aggregate of approximately 375 dosage strengths. The Australian generics market is still underdeveloped and, as a result, the government is increasingly focused on encouraging the use of generics in an effort to reduce costs. Maintaining our position of market leadership as the market undergoes further generic utilization and penetration and continued pricing pressure will be the key to our future success in Australia.

Japan

Mylan Seiyaku Ltd. (”Mylan Seiyaku”), our wholly owned Japanese subsidiary, offers a broad portfolio of more than 360 products in an aggregate of approximately 500 dosage strengths. We also have a manufacturing and packaging facility located in Japan, which is key to serving the Japanese market. Japan is the second largest pharmaceutical market in the world, behind the U.S., and the sixth largest generic prescription market worldwide by value, with sales of approximately $3.3 billion during the twelve months ended November 2012. Currently, the market is largely composed of hospitals and clinics, but pharmacies are expected to play a greater role as generic substitution, aided by recent pro-generics government action, becomes more prevalent. The Japanese government has stated that it intends to grow generic utilization to 30% by the end of March 2013 from approximately 25% at September 30, 2012.

During 2012, we and Pfizer Japan Inc. (“Pfizer Japan”) announced a definitive agreement to establish an exclusive long-term strategic collaboration to develop, manufacture, distribute and market generic drugs in Japan. Under the agreement, both parties will continue to operate separate legal entities in Japan, but will collaborate on current and future generic products, sharing the costs and profits resulting from the collaboration. Mylan Seiyaku’s responsibilities primarily consist of managing operations, including research and development, and manufacturing. Pfizer Japan’s responsibilities under the agreement primarily consist of the commercialization of the combined generics portfolio and managing a combined marketing and sales effort. The collaboration became operational on January 1, 2013.

New Zealand

In New Zealand, our business operates under the name Mylan New Zealand and is the largest generics company in the country. New Zealand is a government tender market where companies submit offers and if accepted can gain exclusivity of up to three years.

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory, severe allergy and psychiatry markets. Mylan Specialty’s portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Mylan Specialty’s revenues are derived through the sale of the EPIPEN® Auto-Injector.

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. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the “Guidelines for the Diagnosis and Management of Food Allergy in the United States.” These guidelines state that epinephrine is the first line treatment for

anaphylaxis. The EPIPEN® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EPIPEN® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our market share.

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

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administration in the maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disorder ("COPD") patients, including those with chronic bronchitis and emphysema. Mylan Specialty has been issued several U.S. and international patents protecting Perforomist® Inhalation Solution.

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

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

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

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

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 or a new delivery system for a drug previously approved under an ANDA.

The ANDA development process is generally less time-consuming and complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and

efficacy conducted for the referenced drug 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 referenced brand drug. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the referenced drug 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 referenced brand drug in

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terms of the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action when administered at the same molar dose under similar conditions.

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

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

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

A number of branded pharmaceutical patent expirations are expected over the next several years. These patent expirations should provide additional generic product opportunities. We intend to concentrate our generic product development activities on branded products with significant sales in specialized or growing markets or in areas that offer significant opportunities and other competitive advantages. In addition, we intend to continue to focus our development efforts on technically difficult-to-formulate products or products that require advanced manufacturing technology.

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

An additional requirement for FDA approval of NDAs and ANDAs is that our manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as current Good Manufacturing Practices (“cGMP”). The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving.

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

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

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

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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 active pharmaceutical ingredients, and improve FDA's communications and feedback with industry.
Under GDUFA, 70% of the total fees will be derived from facility fees paid by finished dosage form manufacturers and active pharmaceutical ingredient facilities listed or referenced in a pending or approved generic drug applications. The remaining 30% of the total fees will be derived from application fees, including generic drug application fees, prior approval supplement fees and drug master file fees.

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

The second track of the approval process is governed by the Patented Medicines NOC Regulations ("Regulations"). The owner or exclusive licensee of patents relating to the brand drug for which it has an NOC may have established a list of patents administered by Health Canada enumerating all the patents claiming the medicinal ingredient, formulation, dosage form or the use of the medicinal ingredient. It is possible that even though the patent for the API may have expired, the originator may have other patents on the list which relate to new forms of the API, a formulation or additional uses. Most brand name drugs have an associated patent list containing one or more unexpired patents claiming the medicinal ingredient itself or a use of the medicinal ingredient (a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms). In its ANDS, a generic applicant must make at least one of the statutory allegations with respect to each patent on the patent list, for example, alleging that the patent is invalid or would not be infringed and explaining the basis for that allegation. In conjunction with filing its ANDS, the generic applicant is required to serve on the originator a Notice of Allegation ("NOA"), which gives a detailed statement of the factual and legal basis for its allegations in the ANDS. The originator may commence a court application within 45 days after it has been served with the NOA, if it takes the position that the allegations are not justified. When the application is filed in court and served on Health Canada, Health Canada may not issue an NOC until the earlier of the determination of the application by the court after a hearing or the expiration of 24 months from the commencement of the application. The period may be shortened or lengthened by the court in certain circumstances. An NOC can be obtained for a generic product only if the generic respondent is successful in dismissing the application under the Regulations in court. The legal costs incurred in connection with the application could be substantial.

Section C.08.004.1 of the Food and Drug Regulations is the so-called data protection provision, and the current version of this section applies in respect of all drugs for which an NOC was issued on or after June 17, 2006. A subsequent applicant for approval to market a drug for which an NOC has already been issued does not need to perform duplicate clinical trials similar to those conducted by the first NOC holder, but is permitted to demonstrate safety and efficacy by submitting data demonstrating that its formulation is bioequivalent to the formulation that was issued for the first NOC. The first party to obtain an NOC for a drug will have an eight-year period of exclusivity

starting from the date it received its NOC based on those clinical data. A subsequent applicant for approval who seeks to establish safety and efficacy by comparing its product to the product that received the first NOC will not be able to file its own application until six years following the issuance of the first NOC have expired. The Minister of Health will not be permitted to issue an NOC to that applicant until eight years following the issuance of the first NOC have expired — this additional two-year period will correspond in most cases to the 24-month automatic stay under the Regulations. If the first person provides the Minister with the description and results of clinical trials relating to the use of the drug in pediatric populations, it will be entitled to an extra six months of data protection. A drug is only entitled to data protection so long as it is being marketed in Canada.

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

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

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

EMEA

The EU presents complex challenges from a regulatory perspective. There is over-arching legislation which is then implemented at a local level by the 27 individual member states, Iceland, Liechtenstein and Norway. Between 1995 and 1998, the legislation was revised in an attempt to simplify and harmonize product registration. This revised legislation introduced the mutual recognition ("MR") procedure, whereby after submission and approval by the authorities of the so-called reference member state ("RMS"), further applications can be submitted into the other chosen member states (known as concerned member states ("CMS")). Theoretically, the authorization of the RMS should be mutually recognized by the CMS. More typically, however, a degree of re-evaluation is carried out by the CMS. In November 2005, this legislation was further optimized. 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 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

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timelines, they will be referred to the coordination group for MR and DCPs and reviewed in a 60-day procedure. If this 60-day procedure does not result in a consensus by all member states, the product can be marketed in the countries whose health authorities agree that the product can be licensed. The issue raised will then enter a second referral procedure.

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

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

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

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

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

An applicant for a generic marketing authorization currently cannot avail itself of the abridged procedure in the EU by relying on the originator pharmaceutical company’s data until expiry of the relevant period of exclusivity given to that data. For products first authorized prior to October 30, 2005, this period is six or ten years (depending on the member state in question and/or the regulatory procedure used by the originator) after the grant of the first marketing authorization sought for the relevant product, due to data exclusivity provisions which have been in place. From October 30, 2005, the implementation of a new EU directive (2004/27/EC) harmonized the data exclusivity period for originator pharmaceutical products throughout the EU member states, which were legally obliged to have implemented the directive by October 30, 2005. The new regime for data exclusivity provides for an eight-year data exclusivity period commencing from the grant of first marketing authorization. After the eight-year period has expired, a generic applicant can refer to the data of the originator pharmaceutical company in order to file an abridged application for approval of its generic equivalent product. Yet, conducting the necessary studies and trials for an abridged application, within the data exclusivity period, is not regarded as contrary to patent rights or to supplementary protection certificates for medicinal products. However, the applicant will not be able to launch its product for an additional two years. This ten-year total period may be extended to 11 years if the original marketing authorization holder obtains, within those initial eight years, a further authorization for a new therapeutic use of the product which is shown to be of significant clinical benefit. Further, specific data exclusivity for one year may be obtained for a new indication for a well-established substance, provided that significant preclinical or clinical studies

were carried out in relation to the new indication. This new regime for data exclusivity applies to products first authorized after October 30, 2005.

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

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

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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.

Asia Pacific

Australia

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

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

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

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

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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 (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. Prior to finalizing listing conditions, negotiations commence between the government Pharmaceutical Benefits Pricing Authority and pharmaceutical suppliers to determine specific pricing details and any risk sharing arrangements necessary to ensure the continued cost effective utilization of the new medicine. 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.

Additional brands of existing PBS listed medicines (generic medicines) are listed upon patent expiry at a price 16% lower than the existing price paid for the original, and with a brand equivalence indicator permitting substitution at pharmacy level. Generic medicines introduce price competition through trading terms offered to pharmacy to encourage brand substitution.

Most importantly for the generic medicines sector, commencing in 2008, the government has introduced PBS reforms designed to significantly reduce the price the government pays for off patent medicines, by taking more immediate advantage of price competition at pharmacy level. In 2010, the government again amended the legislation to further expand and accelerate the PBS price reductions in the off patent market. This reform built on the price reductions on off patent medicines impacted by the 2008 reform, increased the percentage price reduction on the launch of the first generic and mandated a minimum overall price cut on April 1, 2012 for many other off patent medicines not previously covered by the 2008 reform. The ongoing price disclosure system will impose further price reductions based on the weighted average price discount to pharmacists on a rolling basis each year. This has had, and will continue to have for several years beyond 2013, a negative impact on sales and gross profit in this market.

Japan

In Japan, we are governed by various laws and regulations, including the Pharmaceutical Affairs Law (Law No. 145, 1960), as amended, and the Products Liability Law (Law No. 85, 1994).

Under the Pharmaceutical Affairs Law, 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 Minister of Health, Labour and Welfare (the “MHLW”). The authority to grant the Marketing License is delegated to prefectural governors; therefore, the relevant application must be filed with the relevant prefectural governor. A Marketing License will not be granted if the quality control system for the pharmaceutical for which the Marketing License has been applied or the post-marketing safety management system for the relevant pharmaceutical does not comply with the standards specified by the relevant Ministerial Ordinance made under the Pharmaceutical Affairs Law.

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

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

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The Pharmaceutical Affairs Law 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.

API

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

Specialty Segment

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

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

Preclinical tests include laboratory evaluation of the product and its chemistry, formulation and stability, as well as toxicology and pharmacology studies to help define the pharmacological profile of the drug and assess the potential safety and efficacy of the product. The results of these studies are submitted to the FDA as part of the IND. They must demonstrate that the product delivers sufficient quantities of the drug to the bloodstream or intended site of action to produce the desired therapeutic results, before human clinical trials may begin. These studies must also provide the appropriate supportive safety

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information necessary for the FDA to determine whether the clinical studies proposed to be conducted under the IND can safely proceed. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, during that 30-day period, raises concerns or questions about the conduct of the proposed trials, as outlined in the IND. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. In addition, an independent institutional review board must review and approve any clinical study prior to initiation.

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

- Phase I: The drug is initially introduced into a relatively small number of healthy human subjects or patients and is tested for safety, dosage tolerance, mechanism of action, absorption, metabolism, distribution and excretion.
- Phase II: Studies are performed with a limited patient population to identify possible adverse effects and safety risks, to assess the efficacy of the product for specific targeted diseases or conditions, and to determine dosage tolerance and optimal dosage.
- Phase III: When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to evaluate further dosage and clinical efficacy and to test further for safety in an expanded patient population at geographically dispersed clinical study sites.

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

Research and Development

Research and development 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. We have significantly bolstered our global research and development capabilities over the past several years, including through the 2010 acquisition of Bioniche Pharma, which significantly enhanced our injectables platform and our late 2011 acquisition of Pfizer's respiratory delivery platform. In the U.S., our largest market, the FDA is the principal regulatory body with respect to pharmaceutical products. Each of our other markets has separate pharmaceutical regulatory bodies, including, but not limited to, the Agence Nationale de Securite du Medicament et de Sante in France, Health Canada, the Medicines and Healthcare products Regulatory Agency in the U.K., the EMA (a decentralized body of the EU), the Bundesinstitut für Arzneimittel und Medizinprodukte in Germany, the Irish Medicines Board in Ireland, the Agenzia Italiana del Farmaco in Italy, the Agencia Española de Medicamentos y Productos Sanitarios in Spain, the TGA in Australia, the MHLW in Japan, Drug Controller General of India, and the World Health Organization ("WHO"), the regulatory body of the United Nations.

Our global research and development strategy emphasizes the following areas:

- development of both branded and generic finished dose products for the global marketplace, including ARV programs;
- development of monoclonal anti-bodies ("biologics")
- 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 injectable products;
- development of unit dose oral inhalation products for nebulization;
- development of a dry powder inhaler for the treatment of asthma and COPD and other respiratory therapies;
- development of API;
- development of drugs that target smaller, specialized or underserved markets;
- development of generic drugs that represent first-to-file opportunities in the U.S. market;
- expansion of the existing solid oral dosage product portfolio, including with respect to additional dosage strengths;

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- 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 generic biologics in the marketplace and our ability to be successful in this emerging market will depend on the implementation of balanced scientific standards for approval, while not imposing excessive clinical testing demands or other hurdles for well-established products. Furthermore, an efficient patent resolution mechanism and a well-defined mechanism to grant interchangeability after the establishment of biosimilarity with the reference biological product will be key elements determining our future success in this area.

In 2011, we acquired from Pfizer the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline's Advair® Diskus and Seretide® Diskus incorporating Pfizer's proprietary dry powder inhaler delivery platform (the “Respiratory Delivery Platform”). The acquisition of the Respiratory Delivery Platform fills an important strategic gap in our product portfolio and will expand our focus on difficult-to-produce, limited competition products.

We have a robust generic pipeline. As of December 31, 2012, we had approximately 1,000 country level product approvals pending. During 2012, we completed more than 690 global country level product submissions, which included 88 in North America, 375 in EMEA and 229 in Asia Pacific. 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, 2012, we received 675 product approvals globally, including individual country level approvals. Of that total, there were 84 approvals in North America, including 49 in the U.S., 30 in Asia Pacific, 478 country level approvals in EMEA, and 106 country level approvals for ARV products. The 49 approvals in the U.S. consisted of 43 final ANDA approvals and six tentative ANDA approvals. The 106 country level ARV approvals received consisted of 23 products in 35 different countries, with one ARV approval in the U.S. based upon the U.S. President’s Emergency Plan for AIDS Relief.

As of December 31, 2012, we had 183 ANDAs pending FDA approval, representing $79.9 billion in annual sales for the brand name equivalents of these products for the twelve months ended June 30, 2012. Of those pending product applications, 34 were first-to-file Paragraph IV ANDA patent challenges, representing $20.8 billion in annual brand sales for the twelve months ended June 30, 2012. The historic branded drug sales are not indicative of future generic sales, but are included to illustrate the size of the branded product market.

Patents, Trademarks and Licenses

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

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

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

Patents are a key determinant of market exclusivity for most branded pharmaceuticals. Patents provide the innovator with the right to 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

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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 pharmacies, mail order pharmacies and group purchasing organizations. We also market our generic products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, pharmacy benefit management companies and government entities. These customers, called "indirect customers," purchase our products primarily through our wholesale customers.

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

Specialty Segment

Mylan Specialty markets its products to a number of different customer audiences in the U.S., including health care practitioners, wholesalers, pharmacists and pharmacy chains, hospitals, payers, PBMs, HMOs, home health care, long-term care and patients. We reach these customers through our field-based sales force and National Accounts team of approximately 340 employees, to increase our customers' understanding of the unique clinical characteristics and benefits of our branded products. Additionally, Mylan Specialty supports educational programs to consumers and patients.

Major Customers

During 2012, sales to Cardinal Health, Inc. and McKesson Corporation represented approximately 14% and 13% of consolidated net revenues, respectively. During 2011, sales to Cardinal Health, Inc. and McKesson Corporation represented approximately 13% and 11% of consolidated net revenues, respectively. Sales to Cardinal Health, Inc. and

McKesson Corporation represented approximately 11% each of consolidated net revenues during 2010.

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 several of our revenue recognition provisions.

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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 products that compete based on their clinical characteristics and benefits.

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

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

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

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

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

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. Our sales also can be impacted by additional labeling requirements relating to safety or convenience that may be imposed on our products by the FDA or by similar regulatory agencies. If competitors introduce new products and processes with therapeutic or cost advantages, our products can be subject to progressive price reductions and/or decreased volume of sales.

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the “PPACA”) and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. The required rebate is currently 13% of the average manufacturer’s price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer’s price or the difference between the average manufacturer’s price and

the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

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

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

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

Spain. Spain is a rapidly growing, highly fragmented generic market with many participants. As a result of recent legislative changes, all regions within Spain will move to INN prescribing and substitution, thus making the pharmacists the key driver of generic usage. 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.

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

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

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

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

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

The Indian commercial market is a rapidly growing, highly fragmented generic market with a significant number of participants. Companies compete in India based on a wide portfolio, building strong relationships with customers and providing a consistent supply of quality products.

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. Mylan India provides Mylan with significant benefits of vertical integration and continued opportunities as a part of our global pharmaceutical platform. 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.

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Seasonality
Certain parts of our business are affected by seasonality, primarily the Specialty Segment and the Asia Pacific region 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 significant to our annual consolidated results.

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

Employees
Mylan's global workforce includes more than 20,000 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: investor.mylan.com. We make available on or through our Internet website certain reports and amendments to those reports that we file with the Securities and Exchange Commission (the "SEC") in accordance with the Securities Exchange Act of 1934. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q and our current reports on Form 8-K. We make this information available on our website free of charge, as soon as reasonably practicable after we electronically file the information with, or furnish it 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 Securities Exchange Act of 1934.

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

The following risk factors could have a material adverse effect on our business, financial position or results of operations and could cause the market value of our common stock to decline. These risk factors may not include all of the important factors that could affect our business or our industry or that could cause our future financial results to differ materially from historic or expected results or cause the market price of our common stock to fluctuate or decline.

CURRENT ECONOMIC CONDITIONS MAY ADVERSELY AFFECT OUR INDUSTRY, BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Over the past few years, the global economy has undergone a period of significant volatility, and the economic environment may continue to be less favorable than that of past years. In particular, the risk of a debt default by certain European countries and related European financial structuring efforts or deficit reduction programs instituted by the U.S. government could negatively impact the global economy. This has led, and/or could lead, to reduced

consumer and customer spending and/or reduced or eliminated third party payor coverage or reimbursement in the foreseeable future, and this may include spending on health care. While generic drugs present an ideal alternative to higher-priced branded products, our sales could be negatively impacted if patients forego obtaining health care, customers reduce spending or purchases, and/or if third-party payors reduce or eliminate coverage or reimbursement amounts. In addition, reduced consumer and customer spending and/or reduced third party payor coverage or reimbursement, may drive us and our competitors to decrease prices and may reduce the ability of customers to pay their obligations. These conditions may have a material adverse effect on our industry, business, financial position and results of operations and may cause the market value of our common stock to decline.

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OUR INTEGRATION OF ACQUIRED BUSINESSES INVOLVES A NUMBER OF RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

There are a number of operational risks associated with the integration of acquired businesses. These risks include, but are not limited to, difficulties in achieving identified financial and operating synergies, cost savings, revenue synergies and growth opportunities; difficulties in consolidating information technology platforms, business applications and corporate infrastructure; our 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 or domestic and foreign economic conditions.

These factors could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, or otherwise cause a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

WE HAVE GROWN AT A VERY RAPID PACE. OUR INABILITY TO PROPERLY MANAGE OR SUPPORT THIS GROWTH MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We have grown very rapidly over the past few years, through our acquisitions of the former Merck Generics business, the former Matrix Laboratories Limited, Bioniche Pharma and the Respiratory Delivery Platform. This growth has put significant demands on our processes, systems and people. We 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 intense. If we are unable to hire and retain qualified employees and if we do not continue to invest in systems and processes to manage and support our rapid growth, there may be a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

OUR GLOBAL FOOTPRINT EXPOSES US TO ADDITIONAL RISKS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our operations extend to numerous countries outside the U.S., and operating globally exposes us to certain additional risks including, but not limited to:

- compliance with a variety of national and local laws of countries in which we do business, including 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;
- changes in laws, regulations, and practices affecting the pharmaceutical industry and the health care system, including but not limited to imports, exports, manufacturing, cost, pricing, reimbursement, approval, inspection, and delivery of health care;
- fluctuations in exchange rates for transactions conducted in currencies other than the functional currency;
- adverse changes in the economies in which we operate as a result of a slowdown in overall growth, a change in government or economic liberalization policies, or financial, political or social instability in such countries that affects the markets in which we operate, particularly emerging markets;
- wage increases or rising inflation in the countries in which we operate;
- supply disruptions, and increases in energy and transportation costs;

- natural disasters, including droughts, floods and earthquakes in the countries in which we operate;
- communal disturbances, terrorist attacks, riots or regional hostilities in the countries in which we 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. Furthermore, whether due to language, cultural or other differences, statements we make may be misinterpreted, misconstrued or taken out of context. Finally, the internal political stability of, or the relationship

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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 future operations. Any such changes could lead to a decline in our profitability. Any meaningful deterioration of the political stability in and/or diplomatic relations between any countries in which we do business could have a material adverse effect on our operations. Any of the above factors could have a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

A SIGNIFICANT PART OF OUR BUSINESS IS LOCATED IN INDIA AND IS SUBJECT TO REGULATORY, ECONOMIC, SOCIAL AND POLITICAL UNCERTAINTIES IN INDIA. THESE UNCERTAINTIES CREATE RISKS WHICH COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

In recent years, Mylan's Indian subsidiary, Mylan Laboratories Limited, has benefited from many policies of the Government of India and the Indian state governments in the states in which it operates, 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 and economic and fiscal policy in India, including changes in exchange rates and controls, interest rates and taxation policies, as well as social stability and political, economic or diplomatic developments affecting India in the future. In particular, India has experienced significant economic growth over the last several years, but faces major challenges in sustaining that growth in the years ahead. These challenges include the need for substantial infrastructure development and improving access to health care and education. Our ability to recruit, train and retain qualified employees and develop and operate our manufacturing facilities in India could be adversely affected if India does not successfully meet these challenges.

Southern Asia has, from time to time, experienced instances of civil unrest and hostilities among neighboring countries, including India and Pakistan, and within the countries themselves. Rioting, military activity or terrorist attacks in the future could influence the Indian economy by disrupting communications and making travel and the conduct of our business more difficult. Resulting political 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 have a material adverse effect on the market for Mylan Laboratories Limited's products. Furthermore, if India were to become engaged in armed hostilities, particularly hostilities that were protracted or involved the threat or use of nuclear weapons, Mylan Laboratories Limited might not be able to continue its operations. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. These risks could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

MOVEMENTS IN FOREIGN CURRENCY EXCHANGE RATES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

A significant portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including the Euro, the Australian Dollar, the British Pound, the Canadian Dollar, the Indian Rupee and

the Japanese Yen. We report our financial results in U.S. Dollars. 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 exchange rates. In particular, the risk of a debt default by certain European countries and related European financial restructuring efforts may cause volatility in the value of the Euro. 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. These risks could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ARE SUBJECT TO THE U.S. FOREIGN CORRUPT PRACTICES ACT AND SIMILAR WORLDWIDE ANTI-BRIBERY LAWS, WHICH IMPOSE RESTRICTIONS AND MAY CARRY SUBSTANTIAL PENALTIES. ANY VIOLATIONS OF THESE LAWS, OR ALLEGATIONS OF SUCH VIOLATIONS, COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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The U.S. Foreign Corrupt Practices Act and anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business or other commercial advantage. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We operate in jurisdictions that have experienced governmental and private sector corruption to some degree, and, in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. We cannot assure you that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR FUTURE REVENUE GROWTH AND PROFITABILITY ARE DEPENDENT UPON OUR ABILITY TO DEVELOP AND/OR LICENSE, OR OTHERWISE ACQUIRE, AND INTRODUCE NEW PRODUCTS ON A TIMELY BASIS IN RELATION TO OUR COMPETITORS' PRODUCT INTRODUCTIONS. OUR FAILURE TO DO SO SUCCESSFULLY COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our future revenues and profitability will depend, to an extent, upon our ability to successfully develop and/or license, or otherwise acquire and commercialize, new generic and patent or statutorily protected pharmaceutical products in a timely manner. Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and the market is not yet proven. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new 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 position and results of operations and could cause the market value of our common stock to decline.

Before any prescription drug product, including generic drug products, can be marketed, marketing authorization approval is required by the relevant regulatory authorities and/or national regulatory agencies (for example the FDA in the U.S. and the EMA in the EU). The process of obtaining regulatory approval to manufacture and market new and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. Outside the U.S., the approval process may be more or less rigorous, and the time required for approval may be longer or shorter than that required in the U.S. Bioequivalence studies conducted in one country may not be accepted in other countries, 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, may be unable to obtain requisite approvals on a timely basis for new generic or branded products that we may develop, license or otherwise acquire. Moreover, if we obtain regulatory approval for a drug, it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which could in turn restrict our potential market for the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalence testing, as well as in anticipation of the product's launch. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans, business, financial position and results of operations and could cause the market value of our common stock to decline.

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 and margin erosion over the generic product life cycle.

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, provides for a period of 180 days of generic marketing exclusivity for each abbreviated new drug application ("ANDA") applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, the applicant generally enjoys higher market share, net revenues and gross margin for that 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

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within 30 months of the FDA's acceptance of our ANDA. If we are unable to obtain approval or tentative approval within that time period, we may risk forfeiture of such marketing exclusivity. Even if we obtain FDA approval for our generic drug products, if we are not the first ANDA applicant to challenge a listed patent for such a product, we may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on our ability to market that product profitably and on our business, financial position and results of operations, and the market value of our common stock could decline.

In Europe, there is no exclusivity period for the first generic. The EMA or national regulatory agencies may grant marketing authorizations to any number of generics. However, if there are other patents which the brand alleges are relevant, for example, new formulations, the owner of the original brand pharmaceutical may be able to obtain a preliminary injunction in certain European jurisdictions delaying launch of the generic product, depending on local court practices and/or the relevance of the asserted patents.

In addition, in other jurisdictions outside the U.S., we may face similar regulatory hurdles and constraints. If we are unable to navigate our products through all of the regulatory hurdles we face in a timely manner it could adversely affect our product introduction plans, business, financial position and results of operations and could cause the market value of our common stock to decline.

WE EXPEND A SIGNIFICANT AMOUNT OF RESOURCES ON RESEARCH AND DEVELOPMENT EFFORTS THAT MAY NOT LEAD TO SUCCESSFUL PRODUCT INTRODUCTIONS. FAILURE TO SUCCESSFULLY INTRODUCE PRODUCTS INTO THE MARKET COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

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 research and development primarily to enable us to manufacture and market approved pharmaceuticals in accordance with applicable regulations. We also partner with third parties to develop products. Typically, research expenses related to the development of innovative compounds and the filing of marketing authorization applications for innovative compounds (such as NDAs in the U.S.) are significantly greater than those expenses associated with the development of and filing of marketing authorization applications for generic products (such as ANDAs in the U.S. and abridged applications in Europe). As we and our partners continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new 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 and, as a result, we may incur total research and development costs to develop a particular product in excess of what we anticipated. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline.

OUR APPROVED PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY, BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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

- the availability of alternative products from our competitors;
- the price of our products relative to that of our competitors;
- the timing of our market entry;
- the ability to market our products effectively to the retail level; and
- the acceptance of our products by government and private formularies.

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Some of these factors are not within our control. Additionally, continuing 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 products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on our profitability, business, financial position and results of operations, and could cause the market value of our common stock to decline.

OUR BUSINESS IS HIGHLY DEPENDENT UPON MARKET PERCEPTIONS OF US, OUR BRANDS AND THE SAFETY AND QUALITY OF OUR PRODUCTS. OUR BUSINESS OR BRANDS COULD BE SUBJECT TO NEGATIVE PUBLICITY, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Market perceptions of our business are very important to us, especially market perceptions of our brands and the safety and quality of our products. If we, 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, harmful to consumers, then this could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. Also, because we are dependent on market perceptions, negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to be resulting from, our products could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

THE ILLEGAL DISTRIBUTION AND SALE BY THIRD PARTIES OF COUNTERFEIT VERSIONS OF OUR PRODUCTS OR OF STOLEN PRODUCTS COULD HAVE A NEGATIVE IMPACT ON OUR REPUTATION AND A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The 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. The World Health Organization (“WHO”) estimates that more than 10% of medications being sold globally are counterfeit.

Third parties may illegally distribute and sell counterfeit versions of our products, which 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 the API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

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

Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

IF WE OR ANY PARTNER FAIL TO 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. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our success, particularly in our specialty business, depends in part on our or any partner's ability to obtain, maintain and enforce patents, and protect trade secrets, know-how and other proprietary information. Our ability to commercialize any branded product successfully will largely depend upon our or any partner's ability to obtain and maintain patents of sufficient scope to prevent third-parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our branded products business by independently developing and marketing

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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 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, and if patents are issued, they may be insufficient in scope to cover our branded products. 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 much litigation. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the U.S. Patent and Trademark Office or any other governmental agency may commence interference proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR BUSINESS COULD BE NEGATIVELY AFFECTED BY THE PERFORMANCE OF OUR COLLABORATION PARTNERS. SUCH NEGATIVE PERFORMANCE COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We have entered into strategic alliances with partners to develop, manufacture or distribute certain products in various markets. The Company commits substantial effort, funds and other resources to these various collaborations. There is a risk that the investments made by the Company in these collaborative arrangements will not generate financial returns. While we believe our relationships with our partners have been good, disputes or conflicting priorities could be a source of delay or uncertainty as to the expected benefits of the collaboration. A failure or inability of our partners to perform their collaboration obligations could have a material adverse effect on our business, financial position and results of operations and could cause a decline in the market value of our common stock.

WE FACE VIGOROUS COMPETITION FROM OTHER PHARMACEUTICAL MANUFACTURERS THAT THREATENS THE COMMERCIAL ACCEPTANCE AND PRICING OF OUR PRODUCTS. SUCH COMPETITION COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The generic pharmaceutical industry is highly competitive. We face competition from many U.S. and foreign 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 research and development and marketing staffs;
- larger 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.

Any of these factors and others could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

THE USE OF LEGAL, REGULATORY AND LEGISLATIVE STRATEGIES BY COMPETITORS, BOTH BRAND AND GENERIC, INCLUDING "AUTHORIZED GENERICS" AND CITIZEN'S PETITIONS, AS WELL AS THE POTENTIAL IMPACT OF PROPOSED LEGISLATION, MAY INCREASE OUR COSTS ASSOCIATED WITH THE INTRODUCTION OR MARKETING OF OUR GENERIC PRODUCTS, COULD DELAY OR PREVENT SUCH INTRODUCTION AND/OR COULD SIGNIFICANTLY REDUCE OUR PROFIT POTENTIAL. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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Our competitors, both branded and generic, often pursue strategies to prevent or delay 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 generic competition initially enters the market;
- launching a generic version of their own branded product at the same time generic competition initially enters the market;
- filing citizen's petitions with the FDA or other regulatory bodies, 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;
- initiating legislative efforts to limit the substitution of generic versions of brand pharmaceuticals;
- filing suits for patent infringement that may delay regulatory approval of many 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 first generic product for which we seek regulatory approval;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other potential methods;
- persuading regulatory bodies to withdraw the approval of brand name drugs for which the patents are about to expire, thus allowing the brand name company to obtain new patented products serving as substitutes for the products withdrawn; 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 legislation 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 operate were to become effective, 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 position and results of operations and could cause the market value of our common stock to decline.

OUR COMPETITORS, INCLUDING BRANDED PHARMACEUTICAL COMPANIES, OR OTHER THIRD PARTIES, MAY ALLEGE THAT WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY, FORCING US TO EXPEND SUBSTANTIAL RESOURCES IN RESULTING LITIGATION, THE OUTCOME OF WHICH IS UNCERTAIN. ANY UNFAVORABLE OUTCOME OF SUCH LITIGATION, INCLUDING IN AN "AT-RISK LAUNCH" SITUATION, COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Companies that produce brand pharmaceutical products routinely bring litigation against ANDA or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or similar applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic products. 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 would, unless we could obtain a license from the patent holder, need to cease selling in that jurisdiction and may need to deliver up or destroy existing stock in that jurisdiction.

There may also be situations where we use our business judgment and decide to market and sell products, 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 owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent products, patented branded products generally realize a substantially higher profit margin than bioequivalent products. An adverse

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decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR SPECIALTY BUSINESS DEVELOPS, FORMULATES, MANUFACTURES OR IN-LICENSES AND MARKETS BRANDED PRODUCTS THAT ARE SUBJECT TO RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our branded products developed, formulated, manufactured (or alternatively, in-licensed) and marketed by our specialty business may be subject to the following risks, among others:

- limited patent life, or the loss of patent protection;
- competition from generic or similar branded products;
- reductions in reimbursement rates by third-party payors;
- importation by consumers;
- product liability;
- drug development risks arising from typically greater research and development investments than generics; 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 position and results of operations and the market value of our common stock could decline.

A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR REVENUES, GROSS PROFIT OR NET EARNINGS FROM TIME TO TIME. IF THE VOLUME OR PRICING OF ANY OF THESE PRODUCTS DECLINES, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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, 2012 and 2011, our top ten products in terms of sales, in the aggregate, represented approximately 28% and 23%, respectively, of our consolidated total revenues. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

A SIGNIFICANT PORTION OF OUR REVENUES ARE DERIVED FROM SALES TO A LIMITED NUMBER OF CUSTOMERS. ANY SIGNIFICANT REDUCTION OF BUSINESS WITH ANY OF THESE CUSTOMERS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

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 such customer, or if one such customer were to experience difficulty in paying us on a timely basis, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

During the years ended December 31, 2012, 2011 and 2010, sales to Cardinal Health, Inc. were approximately 14%, 13%, and 11%, respectively, and sales to McKesson Corporation were approximately 13%, 11% and 11%, respectively, of consolidated net revenues.

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. THE RESULT OF SUCH DEVELOPMENTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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A significant amount of our sales are to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of generic pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to attempt to extract price discounts on our products. The result of these developments may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE DEPEND TO A LARGE EXTENT ON THIRD-PARTY SUPPLIERS AND DISTRIBUTORS FOR THE RAW MATERIALS, PARTICULARLY THE CHEMICAL COMPOUND(S) COMPRISING THE ACTIVE PHARMACEUTICAL INGREDIENT, THAT WE USE TO MANUFACTURE OUR PRODUCTS AS WELL AS CERTAIN FINISHED GOODS. AN INTERRUPTION IN THE SUPPLY OF SUCH PRODUCTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We typically purchase the active pharmaceutical ingredient (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.

Additionally, we maintain safety stocks in our raw materials inventory and, in certain cases where we have listed only one supplier in our applications with regulatory agencies, have received regulatory agency approval to use alternative suppliers should the need arise. However, there is no guarantee that we will always have timely and sufficient access to a critical raw material or finished product. An interruption in the supply of a single-sourced raw material, including the active ingredient, or finished product could cause our business, financial position and results of operations to be materially adversely affected, and the market value of our common stock could decline. In addition, our manufacturing capabilities could be impacted by quality deficiencies in the products which our suppliers provide, which could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

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

WE HAVE A LIMITED NUMBER OF MANUFACTURING FACILITIES AND CERTAIN THIRD PARTY SUPPLIERS PRODUCING A SUBSTANTIAL PORTION OF OUR PRODUCTS. PRODUCTION AT ANY ONE OF THESE FACILITIES COULD BE INTERRUPTED, WHICH, DEPENDING ON THE FACILITY, COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF

OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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, act of God, civil or political unrest, 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 position and results of operations and could cause the market value of our common stock to decline.

BECAUSE THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED, WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE REGULATIONS. SHOULD WE FAIL TO COMPLY, WE COULD EXPERIENCE MATERIAL ADVERSE EFFECTS ON OUR BUSINESS,

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FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The pharmaceutical industry is subject to regulation by various governmental authorities. For instance, we must comply with requirements of the FDA and similar requirements of similar agencies in our other markets with respect to the research, development, manufacture, quality, safety, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with regulations of the FDA and other regulators could result in fines, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, suspension of the applicable regulator's review of our submissions, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the regulators may also have the authority to revoke previously granted drug approvals. Although we have internal regulatory compliance programs and policies and have had a favorable compliance history, in all material respects, there is no guarantee that these programs, as currently designed, will meet regulatory agency standards in the future. Additionally, despite our efforts at compliance, from time to time we receive notices of observations of FDA inspections as well as official agency correspondence regarding compliance. There is also no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, or if any of the noted risks occur, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

In Europe we must also comply with regulatory requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Some of these requirements are contained in EU regulations and governed by the EMA. Other requirements are set down in national laws and regulations of the EU Member States. Failure to comply with the regulations can result in a range of fines, penalties, product recalls/suspensions or even criminal liability. Similar laws and regulations exist in most of the markets in which we operate.

In addition to the new drug approval process, government agencies also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and other similar regulators. Products manufactured in our facilities must be made in a manner consistent with current good manufacturing practices or similar standards in each territory in which we manufacture. Compliance with such regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. The FDA and other agencies periodically inspect our manufacturing facilities for compliance. Regulatory approval to manufacture a drug is site-specific. Failure to comply with good manufacturing practices and other regulatory standards at one of our manufacturing facilities could result in an enforcement action brought by the FDA or other regulatory bodies which could include withholding or withdrawing the approval of our submissions or other product applications of that facility, discontinuation of manufacture, recalls, or other adverse actions. If any regulatory body were to withhold or withdraw approval of an application, or require a recall or other adverse product action, or require one of our manufacturing facilities to cease or limit production, our business could be adversely affected. Delay and cost in obtaining FDA or other regulatory approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We also must comply with data protection and data privacy requirements in many countries. Compliance with these laws, rules and regulations regarding privacy, security and protection of employee data could result in higher compliance and technology costs for the Company, as well as significant fines, penalties and damage to our global reputation and our brand as a result of non-compliance.

We are subject, as are generally all manufacturers, 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. Although we have not incurred significant costs associated with complying with such environmental provisions in the past, 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 could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS

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WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. The Patient Protection and Affordable Care Act ("PPACA") of 2010 includes a provision requiring the Centers for Medicare and Medicaid Services ("CMS") to publish a weighted average Average Manufacturer Price ("AMP") for all multi-source drugs. The provision was effective October 1, 2010; however, weighted average AMP's have not yet been published by CMS, except in draft form, and have not been implemented for use in the calculation of Federal Upper Limits ("FULs"). Although the weighted average AMP would not reveal Mylan's individual AMP, publishing a weighted average AMP available to customers and the public at large could negatively affect our leverage in commercial price negotiations.

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

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

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 COULD REDUCE PRICES FOR OUR PRODUCTS OR REDUCE OUR MARKET OPPORTUNITIES. ANY SUCH REDUCTIONS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Various governmental authorities (including the U.K. National Health Service and the German statutory health insurance scheme) and private health insurers and other organizations, such as health maintenance organizations ("HMOs") in the U.S., provide reimbursements or subsidies to consumers for the cost of certain pharmaceutical products. Demand for our products depends in part on the extent to which such reimbursement is available. In the U.S., third-party payors increasingly challenge the pricing of pharmaceutical products. This trend and other trends toward the growth of HMOs, managed health care and legislative health care reform create significant uncertainties regarding the future levels of reimbursement for pharmaceutical products. Further, any reimbursement may be reduced in the future, perhaps to the point that market demand for our products declines. Such a decline could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our

common stock to decline.

In addition, a number of markets in which we operate have implemented or may implement tender systems 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. 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 in other markets leading to further price declines, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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LEGISLATIVE OR REGULATORY PROGRAMS THAT MAY INFLUENCE PRICES OF PHARMACEUTICAL PRODUCTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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

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 implement, government mandated price reductions. When such price cuts occur, pharmaceutical companies have generally experienced significant declines in revenues and profitability and uncertainties continue to exist within the market. Such price reductions 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 further material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

HEALTH CARE REFORM LEGISLATION COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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

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

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices. Within the EU and in other countries, the availability of our products in some markets at lower prices undermines our sales in some markets with higher prices. Additionally, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may also impair our ability to obtain

acceptable prices in existing and potential new markets, and may create the opportunity for third party cross border trade.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ARE INVOLVED IN VARIOUS LEGAL PROCEEDINGS AND CERTAIN GOVERNMENT INQUIRIES AND MAY EXPERIENCE UNFAVORABLE OUTCOMES OF SUCH PROCEEDINGS OR INQUIRIES, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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We are or may be involved in various legal proceedings and certain government inquiries, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract and claims involving Medicare and/or Medicaid reimbursements, or laws relating to sales and marketing practices, some of which are described in our periodic reports, that involve claims for, or the possibility of fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties and exclusion from participation in various government health-care-related programs. 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 position and results of operations and could cause the market value of our common stock to decline.

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. 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 position and results of operations and could cause the market value of our common stock to decline.

In addition, in limited circumstances, entities we acquired in the acquisition of the former Merck Generics business are party to litigation in matters under which we are entitled to indemnification by Merck KGaA. However, there are risks inherent in such indemnities and, accordingly, there can be no assurance that we will receive the full benefits of such indemnification, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

IF THE INTERCOMPANY TERMS OF CROSS BORDER ARRANGEMENTS WE HAVE AMONG OUR SUBSIDIARIES ARE DETERMINED TO BE INAPPROPRIATE, OUR TAX LIABILITY MAY INCREASE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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 in relation to various aspects of our business, including manufacturing, marketing, sales and delivery functions. Although we believe our cross border arrangements between affiliates are based upon internationally accepted standards, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in their country, which may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase. This could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

UNANTICIPATED CHANGES IN OUR TAX PROVISIONS OR EXPOSURE TO ADDITIONAL INCOME TAX LIABILITIES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We are subject to income taxes in the U.S. and many foreign jurisdictions. Significant judgment is 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 historical 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 position and results of operations and could cause the market value of our common stock to decline.

CHANGES IN INCOME TAX LAWS AND TAX RULINGS MAY HAVE A SIGNIFICANTLY ADVERSE IMPACT ON OUR EFFECTIVE TAX RATE AND INCOME TAX EXPENSE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Potential changes to income tax laws in the United States 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

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associated with transfers of intangibles offshore; and limit earnings stripping by expatriated entities. In addition, proposals were 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 ameliorate 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. This could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY DECIDE TO SELL ASSETS, WHICH COULD ADVERSELY AFFECT OUR PROSPECTS AND OPPORTUNITIES FOR GROWTH, AND WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We may from time to time consider selling certain assets if (a) we determine that such assets are not critical to our strategy, or (b) we believe the opportunity to monetize the asset is attractive or for various reasons including we want to reduce indebtedness. We have explored and will continue to explore the sale of certain non-core assets. Although our intention is to engage in asset sales only if they advance 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 position and results of operations and could cause the market value of our common stock to decline.

WE HAVE SIGNIFICANT INDEBTEDNESS WHICH COULD ADVERSELY EFFECT OUR FINANCIAL POSTION 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 THAT MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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, 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, 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 position and results of operations and could cause the market value of our common stock to decline.

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Our credit facilities, senior unsecured notes, 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 Senior Credit Agreement requires us to maintain specified financial ratios. We cannot assure you that these covenants will not adversely affect our ability to finance our future operations or capital needs or to pursue available business opportunities. A breach of any of these covenants or our inability to maintain the required financial ratios could result in a default under the related indebtedness. If a default occurs, the relevant lenders could elect to declare our indebtedness, together with accrued interest and other fees, to be immediately due and payable. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

Under applicable accounting rules, the cash conversion feature that is a term of the Cash Convertible Notes must be recorded as a liability on our balance sheet and periodically marked to fair value. If our stock price increases, the liability associated with the cash conversion feature would increase and, because this liability must be periodically marked to fair value on our balance sheet, the total amount of indebtedness related to the notes that is shown on our balance sheet would also increase. This could have adverse effects on us, including under any future debt agreements that contain covenants based on a definition of total indebtedness as defined under accounting principles generally accepted in the United States of America ("GAAP"). As a result, we may not be able to comply with such covenants in the future, which could, among other things, restrict our ability to grow our business, take advantage of business opportunities or respond to competitive pressures. Any of the foregoing could have a material adverse effect on our business, financial position and results of operations and could cause the market value of the notes and our common stock to decline.

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

cause the market value of our common stock to decline.

ANY FUTURE ACQUISITIONS OR DIVESTITURES WOULD INVOLVE A NUMBER OF INHERENT RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We may continue to seek to expand our product line through complementary or strategic acquisitions of other companies, products or assets, including those in rapidly developing economies, or through joint ventures, licensing agreements or other arrangements or may determine to divest certain products or assets. Any such acquisitions, joint ventures or other business combinations may involve significant challenges in integrating the new company's operations, and divestitures could be equally challenging. Either process may prove to be complex and time consuming and require substantial resources and effort. It may also disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, regulators and others with whom we have business or other dealings.

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We may be unable to realize synergies or other benefits, including tax savings, expected to result from any acquisitions, joint ventures or other transactions or investments we may undertake, or 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 alter the anticipated benefits of any such transactions. We may also compete for certain acquisition targets with companies having greater financial resources than us or other advantages over us that may prevent us from acquiring a target. We also may inherit legal, regulatory and other risks that accrued prior to the acquisition, whether known or unknown to us. These factors could impair our growth and ability to compete, require us to focus additional resources on integration of operations rather than other profitable areas, or otherwise cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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 EVENT THAT WE WOULD HAVE TO PERFORM UNDER THESE INDEMNIFICATION PROVISIONS, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

In the normal course of business, we periodically enter into employment, legal settlement, and other agreements which incorporate indemnification provisions. 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 our coverage or should coverage be denied, our business, financial position and results of operations could be materially adversely affected and the market value of our common stock could decline.

OUR FUTURE SUCCESS IS HIGHLY DEPENDENT ON OUR CONTINUED ABILITY TO ATTRACT AND RETAIN KEY PERSONNEL. ANY FAILURE TO ATTRACT AND RETAIN KEY PERSONNEL COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

It is important that we attract and retain qualified personnel in order to develop new products and compete effectively. If we fail to attract and retain key scientific, technical 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. If we are unsuccessful in retaining our key employees, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ARE IN THE PROCESS OF ENHANCING AND FURTHER DEVELOPING OUR GLOBAL ENTERPRISE RESOURCE PLANNING SYSTEMS AND ASSOCIATED BUSINESS APPLICATIONS. AS WITH ANY ENHANCEMENTS OF SIGNIFICANT SYSTEMS, DIFFICULTIES ENCOUNTERED COULD RESULT IN BUSINESS INTERRUPTIONS, AND COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We are enhancing and further developing our global enterprise resource planning (“ERP”) systems and associated applications to provide more operating efficiencies and effective management of our business operations. Such changes to ERP systems and related software 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 position and results of operations and could cause the market value of our common stock to decline.

WE ARE INCREASINGLY DEPENDENT ON INFORMATION TECHNOLOGY AND OUR SYSTEMS AND INFRASTRUCTURE FACE CERTAIN RISKS, INCLUDING CYBERSECURITY AND DATA LEAKAGE RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We are increasingly dependent on information technology systems and infrastructure. Any significant breakdown, invasion, destruction or interruption of these systems by employees, others with authorized access to our systems, or unauthorized persons could negatively impact operations. There is also a risk that we could experience a business interruption, theft of information, or reputational damage as a result of a cyber attack, such as an infiltration of a data center, or data leakage of confidential information either internally or at our third-party providers. While we have invested heavily in the protection of

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our data and information technology to reduce these risks, there can be no assurance that our efforts will prevent breakdowns or breaches. If we experience such a breach or breakdown, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

THE EXPANSION OF SOCIAL MEDIA PLATFORMS PRESENT NEW RISKS AND CHALLENGES. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The inappropriate use of certain media vehicles could cause brand damage or information leakage or could lead to legal implications from the improper collection and/or dissemination of personally identifiable information. In addition, negative posts or comments about us on any social networking web site could seriously damage our reputation. Further, the disclosure of non-public company sensitive information through external media channels could lead to information loss as there might not be structured processes in place to secure and protect information. If our non-public sensitive information is disclosed or if our reputation is seriously damaged through social media, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MUST MAINTAIN ADEQUATE INTERNAL CONTROLS AND BE ABLE, ON AN ANNUAL BASIS, TO PROVIDE AN ASSERTION AS TO THE EFFECTIVENESS OF SUCH CONTROLS. FAILURE TO MAINTAIN ADEQUATE INTERNAL CONTROLS OR TO IMPLEMENT NEW OR IMPROVED CONTROLS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Effective internal controls are necessary for Mylan to provide reasonable assurance with respect to its financial reports. We are spending a substantial amount of management 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 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 position and results of operations, and the market value of our common stock could decline.

THERE ARE INHERENT UNCERTAINTIES INVOLVED IN ESTIMATES, JUDGMENTS AND ASSUMPTIONS USED IN THE PREPARATION OF FINANCIAL STATEMENTS IN ACCORDANCE WITH 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 CONSOLIDATED FINANCIAL STATEMENTS, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS,

FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The Consolidated and Condensed Consolidated Financial Statements included in the periodic reports we file with the SEC are prepared in accordance with GAAP. The preparation of financial statements in accordance with 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 position and results of operations and could cause the market value of our common stock to decline.

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CHARGES TO EARNINGS RESULTING FROM ACQUISITIONS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Under the GAAP business combination 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 position and results of operations and could cause the market value of the common stock to decline.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

The Company’s corporate headquarters is located in Canonsburg, Pennsylvania. At December 31, 2012, we owned six production, distribution and warehousing facilities in the U.S. and Puerto Rico. Our major production and distribution sites include Morgantown, West Virginia; Greensboro, North Carolina; Caguas, Puerto Rico; and St. Albans, Vermont. The Company also maintains an administrative office for Mylan Specialty in Basking Ridge, New Jersey.

We own production, distribution and warehousing facilities in eight countries outside the U.S. and Puerto Rico, which include major production and distribution facilities in India, Ireland, Australia and Japan.

Our U.S. research and development facilities are primarily located in Morgantown, West Virginia. Our principal international research and development facilities are located in Ireland and India, with additional sites in the U.K. and Japan.

The Company also leases warehousing, distribution and administrative facilities in numerous locations, both within and outside of the U.S., including properties in New York, France, India and the U.K.

We believe that all 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.

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ITEM 3. Legal Proceedings

For information regarding legal proceedings, refer to Note 15, “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

Our common stock is traded on the NASDAQ Stock Market under the symbol "MYL." The following table sets forth the quarterly high and low sales prices for our common stock for the periods indicated:

Year Ended December 31, 2012	High	Low
Three months ended March 31, 2012	$23.88	$20.37
Three months ended June 30, 2012	23.63	20.21
Three months ended September 30, 2012	24.67	21.20
Three months ended December 31, 2012	28.50	23.25

Year Ended December 31, 2011	High	Low
Three months ended March 31, 2011	$24.17	$20.95
Three months ended June 30, 2011	25.46	21.91
Three months ended September 30, 2011	25.00	16.99
Three months ended December 31, 2011	21.84	15.49

As of February 20, 2013, there were approximately 130,315 holders of record of our common stock, including those held in street or nominee name.

On November 15, 2010, the conversion of the 6.50% mandatorily convertible preferred stock into 125,234,172 shares of our common stock was completed.

The Company does not expect to pay dividends on its common stock in the near future.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

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 31, 2012	—	$—	—	$—
November 1 - November 30, 2012	3,716,773	$27.05	3,716,773	$399,454,812
December 1 - December 31, 2012	14,290,851	$27.95	14,290,851	$—
Total	18,007,624	$27.76	18,007,624	$—

(1) On November 20, 2012, the Company announced that its Board of Directors had approved the repurchase of up to $500 million of the Company's common stock in the open market or through other methods. The repurchase was completed by December 31, 2012.

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

(3) Average price per share includes commissions.

In the past three years, we have issued unregistered securities in connection with the following transactions:
In December 2012, we issued $750.0 million of 3.125% Senior Notes due 2023 (“2023 Senior Notes”). These notes were issued in a private offering exempt from the registration requirements of the Securities Act to qualified institutional buyers in accordance with Rule 144A and to persons outside of the United States pursuant to Regulation S under the Securities Act.

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In November 2010, we issued $800.0 million aggregate principal amount of 6.0% Senior Notes due 2018 (the "2018 Senior Notes"). These notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (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.

In May 2010, we issued $550.0 million of 7.625% Senior Notes due 2017 (the "2017 Senior Notes") and $700.0 million of 7.875% Senior Notes due 2020 (the "2020 Senior Notes"). These notes were issued in private offerings 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. In July 2010, we privately placed $300.0 million aggregate principal amount of senior notes through a reopening of our 2020 Senior Notes.

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, 2008, 2009, 2010, 2011 and 2012 of $100 invested on December 31, 2007 in Mylan's Common Stock, the Standard & Poor's 500 Index and the Dow Jones U.S. Pharmaceuticals Index.

	12/07	12/08	12/09	12/10	12/11	12/12
Mylan Inc.	100.00	70.34	131.08	150.28	152.63	195.23
S&P 500	100.00	63.00	79.67	91.67	93.61	108.59
Dow Jones U.S. Pharmaceuticals	100.00	81.85	97.47	99.55	118.11	134.52

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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” 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.

	Year Ended December 31,				
(In thousands, except per share amounts)	2012 [1]	2011 [2]	2010 [3]	2009 [4]	2008 [5][6]
Statements of Operations:					
Total revenues	$6,796,110	$6,129,825	$5,450,522	$5,092,785	$5,137,585
Cost of sales	3,887,806	3,566,461	3,233,125	3,018,313	3,067,364
Gross profit	2,908,304	2,563,364	2,217,397	2,074,472	2,070,221
Operating expenses:					
Research and development	401,341	294,728	282,146	275,258	317,217
Goodwill impairment	—	—	—	—	385,000
Selling, general and administrative	1,400,747	1,214,631	1,086,609	1,050,145	1,053,485
Litigation settlements, net	(3,133)	48,556	127,058	225,717	16,634
Earnings from operations	1,109,349	1,005,449	721,584	523,352	297,885
Interest expense	308,699	335,944	331,462	318,496	380,779
Other income (expense), net	3,429	(14,869)	(34,178)	22,119	11,337
Earnings (loss) before income taxes and noncontrolling interest	804,079	654,636	355,944	226,975	(71,557)
Income tax provision (benefit)	161,145	115,833	10,402	(20,773)	128,550
Net (earnings) loss attributable to the noncontrolling interest	(2,084)	(1,993)	(427)	(15,177)	4,031
Net earnings (loss) attributable to Mylan Inc. before preferred dividends	640,850	536,810	345,115	232,571	(196,076)
Preferred dividends	—	—	121,535	139,035	139,035
Net earnings (loss) attributable to Mylan Inc. common shareholders	$640,850	$536,810	$223,580	$93,536	$(335,111)
Selected Balance Sheet data:					