MYLAN INC.
Form 10-K
February 21, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

þ **Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2011

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. ¨

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. (Check one):

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, 2011, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $10,469,135,790.

The number of shares outstanding of common stock of the registrant as of February 15, 2012, was 426,933,895.

INCORPORATED BY REFERENCE

Document	Parts of Form 10-K into Which Document is Incorporated
Proxy Statement for the 2012 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, 2011.	III

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MYLAN INC.

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For the Year Ended December 31, 2011

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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 th 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 150 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 into an established worldwide pharmaceutical leader and is currently the third largest generic and specialty pharmaceuticals company 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, most recently, the respiratory delivery platform as described below, 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 September 2010, Mylan completed the acquisition of 100% of the outstanding equity in Bioniche Pharma, a privately held, global injectable pharmaceutical company. Bioniche Pharma manufactures and sells a diverse portfolio of injectable products across several therapeutic areas for the hospital setting. The addition of Bioniche Pharma has strengthened our position in the institutional marketplace, as it augments the portfolio of products we have historically offered to this sector through certain of our North American subsidiaries.

On December 23, 2011, Mylan completed the acquisition of the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline s Advair® Diskus and Seretide® Diskus incorporating Pfizer Inc. s, (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 the Company s product portfolio and will expand the Company s focus on difficult-to-produce, limited competition products, and it will serve as a base for Mylan s respiratory franchise. The Respiratory Delivery Platform and scientific expertise will also be used to develop additional branded specialty products, building upon the capabilities and assets that the Company has in place within the Specialty segment. As part of the agreement, Mylan will fund the remaining development and capital requirements to bring the products to market.

Through Mylan Laboratories Limited, an Indian subsidiary, we manufacture and supply low cost, high quality API for our own products and pipeline, as well as for third parties. Mylan Laboratories Limited is one of the world s largest API manufacturers as measured by the number of drug master files (DMFs) filed with regulatory agencies. Mylan Laboratories Limited is also a leader in supplying API for the manufacturing of antiretroviral (ARV) drugs, which are utilized in the treatment of HIV/AIDS. Additionally, Mylan Laboratories Limited offers a line of finished dosage form (FDF) products in the ARV market and manufactures non-ARV FDF products that are marketed by Mylan. Mylan holds approximately 98% ownership and control in Mylan Laboratories Limited.

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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 delivery products.

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

We believe that the breadth and depth of our business 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, which is included within the Asia Pacific region in our Generics Segment. Our specialty pharmaceutical business is conducted by Dey Pharma, L.P. (Dey). Refer to Note 12 to Consolidated Financial Statements included in Item 8 in this Form 10-K for additional information related to our segments.

Generics Segment

North America

The U.S. generics market is the largest in the world, with generic prescription market revenues of $47.5 billion for the twelve months ended November 2011. Mylan holds the number two ranking in the U.S. generics prescription market in terms of both revenue 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 Mylan Institutional (MI). MI, a business platform created in 2010, that combined the product lines of Mylan Institutional LLC (formerly Bioniche Pharma USA, LLC) and Mylan Institutional Inc. (formerly UDL Laboratories, Inc.), Mylan s unit dose business, both of which are wholly-owned subsidiaries.

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 340 products, of which approximately 305 are in capsule or tablet form in an aggregate of approximately 740 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 four transdermal patch products in a total of 18 dosage strengths that are developed and manufactured by Mylan Technologies, Inc. (MTI), our wholly-owned

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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.

MI 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, veterinary clinics and retail outlets. MI re-packages and markets 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 30 injectable products (branded and generic) in a total of approximately 55 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 80 dosage strengths under supply and distribution agreements with other pharmaceutical companies.

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, which continues 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 retail prescription market by value and the fourth largest generic retail prescription market by volume with revenues of $5.1 billion for the twelve months ended November 2011. MPC offers a portfolio of approximately 115 products in an aggregate of approximately 250 dosage strengths, and currently ranks fifth in terms of market share in the generic retail prescription market in Canada, based on value. 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.

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, the generic retail prescription market in Germany is the largest, followed by France, the United Kingdom (U.K.), Spain and Italy, respectively. Of the top ten generic retail 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 top three market share position in Belgium, Portugal and the Netherlands. We also hold a top three market share position in the generic prescription market in the U.K.

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The European generic retail 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 the Netherlands, Germany, the U.K. and Poland, are characterized by relatively high generic penetration, ranging between 50% and 72% of total retail prescription market sales in the twelve months ended November 2011, based on volume. Conversely, other major European markets, including France, Italy and Spain, are characterized by much lower generic penetration, ranging between 16% and 32% of total retail prescription sales in the twelve months ended November 2011, based on volume. However, recent actions taken by governments, in particular in these latter countries, to reduce healthcare costs could encourage further use of generic pharmaceutical products. In each of these underpenetrated markets, in addition to growth from new product launches, we expect our future growth to be driven by increased generic utilization.

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 their 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 retail portfolio of approximately 215 products in an aggregate of approximately 455 dosage strengths. In France, we have the highest market share, based on value, in the company-branded generic retail 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 penetration.

Italy

In Italy, we market through our subsidiary Mylan S.p.A. a portfolio of approximately 150 products in an aggregate of approximately 285 dosage strengths. In Italy, we have the second highest market share, based on value and volume, in the company-branded generic retail prescription market. We believe that the Italian generic market is underpenetrated, with company-branded retail generics representing approximately 8% of the value of the Italian pharmaceutical retail market. 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 generics penetration and new product launches.

Spain

In Spain, we market through our subsidiary Mylan Pharmaceuticals S.L. a portfolio of approximately 100 products in an aggregate of approximately 220 dosage strengths. In Spain, we have the seventh highest market share, based on value, in the company-branded generic retail prescription market. The company-branded generic market made up approximately 12% of the total Spanish retail pharmaceutical market by value for the twelve months ended November 2011. We view further generic 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 150 products in an aggregate of approximately 330 dosage strengths. In Germany, we have the sixth highest market share, based on

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value, in the company-branded generic retail prescription market. A tender system has been implemented in Germany, and as a result, health insurers play a major role in this market. Under a tender system, health insurers invite manufacturers to submit bids that establish prices for generic pharmaceuticals. Pricing pressures result from an effort to win the tender. As a result of these tenders, our business in Germany has 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 175 products in an aggregate of approximately 315 dosage strengths. Mylan is ranked third in the U.K. generic prescription market, in terms of value, with an estimated market share of approximately 8%. Mylan is well positioned in the U.K. as a preferred supplier to wholesalers and is also focused on areas such as multiple retail pharmacies and hospitals. The 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 retail prescription markets, including Portugal, the Netherlands, and Belgium, where we hold the third highest market share in terms of value, and Sweden where we have the fourth highest market share in terms of value. We also operate in several markets in Central and Eastern Europe, including 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, New Zealand, India, Japan and Taiwan. Additionally, we market API to third parties, as well as supply to other Mylan subsidiaries, through our Indian subsidiary, Mylan Laboratories Limited. We have the highest market share in both the Australia and New Zealand generic pharmaceuticals markets.

Australia

The generic pharmaceutical market in Australia had sales of approximately $1.8 billion during the twelve months ended August 2011. Through our wholly owned subsidiary Alphapharm, we have the highest market share with an estimated 47% market share by volume in Australia, and we offer a portfolio of approximately 170 products in an aggregate of approximately 440 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 penetration and continued pricing pressure will be the key to our future success in Australia.

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.

Japan

Mylan Seiyaku, our wholly owned Japanese subsidiary, offers a broad portfolio of more than 380 products in an aggregate of approximately 500 dosage strengths. We also have a manufacturing and packaging facility

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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 retail prescription market worldwide, with sales of approximately $5.2 billion during the twelve months ended November 2011. 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 23% currently.

Mylan Laboratories Limited

At Mylan Laboratories Limited, our finished dosage business primarily produces ARV products, which are sold mostly outside of India, and other FDF products, which are sold to third parties by other Mylan operations around the world. Additionally, Mylan Laboratories Limited offers a line of FDF products in the ARV market and manufactures non-ARV FDF products that are marketed by Mylan. Expansion of this portfolio and an increase in product sales within India 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 Laboratories Limited is also a leading supplier of generic ARV APIs used in the treatment of HIV/AIDS.

Mylan Laboratories Limited has eight API and intermediate manufacturing facilities and two FDF facilities. One of the API and intermediate manufacturing facilities is located in China, with the remainder in India. Seven of the facilities, including one FDF facility, are FDA approved, which makes Mylan Laboratories Limited 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.

Specialty Segment

Our specialty pharmaceutical business is conducted through Dey, which competes primarily in the respiratory, severe allergy and psychiatry markets. Dey s portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Dey s revenues are derived through the sale of the EpiPen® Auto-Injector. In February 2012, the Company announced that it plans to change the name of Dey to Mylan Specialty.

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. Dey has worldwide rights to the epinephrine auto-injector, which is supplied to Dey 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 with more than 95% market share in the U.S. and more than 90% market share worldwide in the defined auto-injector market during 2011. The strength of the EpiPen brand name, quality and ease of use of the product and the promotional strength of the Dey U.S. sales force have enabled us to maintain our market share.

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Perforomist® Inhalation Solution, Dey s formoterol fumarate inhalation solution, was launched in October 2007. Perforomist Inhalation Solution is a long-acting beta$_2$-adrenergic agonist indicated for long-term, twice-daily administration in the maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disorder (COPD) patients, including those with chronic bronchitis and emphysema. Dey 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 after the end of patent protection or other market exclusivities due to physician and consumer loyalties.

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 circumvention 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.

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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 compares the bioavailability of one drug product with that of the referenced drug product containing the same active ingredient. When established, bioequivalence confirms the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Bioavailability indicates 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.

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, that generic equivalent may be able to be marketed 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 is studied for pediatric indications.

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 large number of high-value 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 in the United States 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.

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In 2010, the FDA held a public hearing for all stakeholders to provide input concerning scientific and technical aspects of the agency s implementation of the statute followed by discussions with industry stakeholders on the introduction of user fees. Mylan is a very active participant in this process.

One 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 Canada, the registration process for approval of all generic pharmaceuticals has two tracks which 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

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

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

The provinces and territories in Canada operate drug benefit programs through which eligible recipients receive drugs through public funding; these drugs are listed on provincial or territorial Drug Benefit Formularies (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 to be approved through a national common drug review process. The listing recommendation is made by the Canadian Expert Drug Advisory Committee and must be approved by the applicable provincial/territorial health ministry.

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. 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.

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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 does not require a national marketing authorization to have been granted for the medicinal product. The pharmaceutical company applies for marketing authorization simultaneously in all the member states of the EU in which it wants to market the product. After consultation with the pharmaceutical company, one of the member states concerned in the DCP will become the RMS. The competent agency of the RMS undertakes the scientific evaluation of the medicinal product on behalf of the other CMSs and coordinates the procedure. If all the member states involved (RMS and CMS) agree to grant marketing authorizations, this decision forms the basis for the granting of the national marketing authorizations in the respective member states.

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

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

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

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

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

Before a generic pharmaceutical product can be marketed in the EU, a marketing authorization must be obtained. If a generic pharmaceutical product is shown to be essentially the same as, or bioequivalent to, one that is already on the market and which has been authorized in the EU for a specified number of years, as explained in the section on data exclusivity below, no further preclinical or clinical trials are required for that new generic pharmaceutical product to be authorized. The generic applicant can file an abridged application for marketing authorization, but in order to take advantage of the abridged procedure, the generic manufacturer must demonstrate specific similarities, including bioequivalence, to the already authorized product. Access to clinical

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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.

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

Certain markets in which Mylan does business have recently undergone, some for the first time, or will soon undergo, government-imposed price reductions or similar pricing pressures on pharmaceutical products. In addition, a number of markets in which we operate have implemented or may implement tender 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.

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) 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 pre-clinical 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.

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, as it subsidizes purchases of most pharmaceutical products through the Pharmaceutical Benefits Scheme (PBS) that has been in place since 1948. The Australian government agency, 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.

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The government exerts a significant degree of control over the pharmaceuticals market through the PBS, which is a governmental program for subsidizing the cost of pharmaceuticals to Australian consumers. More than 80% of all prescription medicines sold in Australia are reimbursed by the PBS. The PBS is operated under the Commonwealth of Australia s (Cth) National Health Act 1953. This statute governs matters such as who may sell pharmaceutical products, the prices at which pharmaceutical products may be sold and governmental subsidies. Commencing in 2008, Australia has undergone government-imposed reforms designed to significantly reduce the price the government pays for off patent medicines. In 2010, the government passed an act of parliament to further expand and accelerate the price reductions in the off patent market. This reform imposed further price reductions on off patent medicines impacted by the 2008 reform, an increased price reduction on the launch of the first new product brand and mandated a minimum average 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 could continue to have, a negative impact on sales and gross profit in this market.

For the first listing of a pharmaceutical product on the PBS, the price is determined through a full health economic analysis submitted to the Pharmaceutical Benefits Advisor Committee (a governmental advisory committee) which then makes a recommendation to the government to consider listing the product on the PBS and then negotiations commence between the Pharmaceutical Benefits Pricing Authority (a governmental agency) and pharmaceutical suppliers to determine the price and any risk sharing arrangements. 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.

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

Manufacturers and suppliers of pharmaceutical products are also regulated by the TGA, which administers the Therapeutic Goods Act 1989 (Cth) (the Act). 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.

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 and providing for evaluation of, therapeutic goods for use in humans and lists therapeutic goods which are approved for supply in, or export from, Australia. Whether a product is listed or registered in the ARTG depends largely on the ingredients, the dosage form of the product and the promotional or therapeutic claims made for the product.

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.

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Japan

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

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

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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 state medical 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 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.

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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 the