MYLAN INC.
Form 10-K
February 26, 2010

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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, 2009

OR

o **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
6.50% Mandatory Convertible Preferred Stock	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 o

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 o 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 o

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 o No o

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. o

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 o
Non-accelerated filer o	(Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o 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, 2009, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $3,906,829,317.

The number of shares outstanding of common stock of the registrant as of February 19, 2010, was 306,679,038.

* The registrant has not yet been phased into the interactive data requirements.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Parts of Form 10-K into which Document is Incorporated
Proxy Statement for the 2010 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, 2009.	III

MYLAN INC.

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PART I

ITEM 1. Business

Mylan Inc. and its subsidiaries (the Company , Mylan , our or we) comprise a global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic and branded generic pharmaceuticals, specialty pharmaceuticals and active pharmaceutical ingredients (API). The Company was incorporated in Pennsylvania in 1970. The Company amended its articles of incorporation to change its name from Mylan Laboratories Inc. to Mylan Inc., effective October 2, 2007.

Effective October 2, 2007, the Company amended its bylaws, to change the Company s fiscal year from beginning April 1st and ending on March 31st, to beginning January 1st and ending on December 31st.

Overview

Long considered a leader in the United States (U.S.) generic pharmaceutical market, Mylan has grown into a worldwide pharmaceutical leader and is currently the third largest generic and specialty pharmaceutical company in the world, in terms of revenues. This evolution has taken place through organic growth and external expansion. Organically, we have attained a position of leadership in the U.S. generic pharmaceutical industry through our ability to obtain Abbreviated New Drug Application (ANDA) approvals and our reliable supply chain. Through the acquisition of Matrix Laboratories Limited (Matrix) and the acquisition of Merck KGaA s generics and specialty pharmaceutical business (the former Merck Generics business), we have created a horizontally and vertically integrated platform with global scale, a diversified product portfolio and an expanded range of capabilities that position us well for the future. We believe that as a result of these acquisitions we are less dependent on any single market or product and are able to compete successfully on a global basis.

Through Matrix, an Indian subsidiary, we manufacture and supply low cost, high quality API for our own products and pipeline, as well as for third parties. Matrix is one of the world s largest API manufacturers with respect to the number of drug master files (DMFs) filed with regulatory agencies. Matrix is also a leader in supplying API for the manufacturing of anti-retroviral (ARV) drugs, which are utilized in the treatment of HIV/AIDS. Additionally, Matrix offers a line of finished dosage form (FDF) products in both the ARV and non-ARV markets.

Matrix had been an Indian listed company in which Mylan owned a 71.2% controlling interest. During 2009, pursuant to the completion of a voluntary delisting offer, Mylan purchased additional shares of Matrix from its then minority shareholders, bringing both the Company s total ownership and control to over 96%. Matrix s stock was delisted from the Indian stock exchanges effective August 21, 2009.

The acquisition of the former Merck Generics business has provided Mylan a worldwide commercial footprint, 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 and allergy products.

Currently, Mylan markets more than 900 different products covering a vast array of therapeutic categories, to consumers in more than 140 countries and territories across the globe. We offer an extensive range of dosage forms and delivery systems, including oral solids, topicals, liquids and semi-solids, as well as some which are difficult to formulate and manufacture and typically have longer product life cycles than traditional generic pharmaceuticals, including high potency formulations, steriles, injectables, transdermal patches, controlled release and respiratory delivery products.

Mylan also has the deepest pipeline and largest number of products pending regulatory approval in the Company s history. Mylan will benefit from substantial operational efficiencies and economies of scale from increased sales volumes and its vertically and horizontally integrated platform.

We believe that the breadth and depth of our business provides certain competitive advantages over many of our competitors in major markets. These advantages include global research and development and manufacturing facilities that provide for additional technologies, economies of scale and a broad product portfolio, as well as an API business, which ensures a high quality, stable supply.

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Our Operations

Mylan previously had three reportable segments, Generics , Specialty and Matrix. The Matrix Segment had consisted of Matrix. Following the acquisition of approximately 25% of the remaining interest in Matrix and its related delisting from the Indian stock exchanges, Mylan now has two reportable segments, Generics and Specialty. Mylan changed its segments to align with how the business is being managed after those changes. The former Matrix Segment is included within the Generics Segment. Information for earlier periods has been recast. Refer to Note 17 to Consolidated Financial Statements included elsewhere in this Form 10-K for additional information related to our segments.

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 Australia, India, Japan and New Zealand (collectively, Asia Pacific). Our API business is conducted through our Indian subsidiary, Matrix, which is included within the Asia Pacific region in our Generics Segment. Our specialty pharmaceutical business is conducted by Dey Pharma, L.P. (Dey).

Generics Segment

North America

The U.S. generics market is the largest in the world, with revenues of $34.4 billion for the twelve months ended November 2009. Mylan holds the number two ranking in the U.S. generics market in terms of both revenue and prescriptions dispensed. Our sales are derived principally through Mylan Pharmaceuticals Inc. (MPI) and UDL Laboratories, Inc. (UDL), our wholly-owned subsidiaries. MPI is our primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary. MPI s net revenues are derived primarily from the sale of solid oral dosage products. Additionally, MPI s net revenues are augmented by transdermal patch products that are developed and manufactured by Mylan Technologies, Inc. (MTI), our wholly-owned transdermal technology subsidiary. UDL primarily re-packages and markets products either obtained from MPI or purchased from third parties, in unit dose formats, for use primarily in hospitals and other medical institutions.

In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 224 products, of which approximately 206 are in capsule or tablet form in an aggregate of approximately 532 dosage strengths. Included in these totals are 25 extended release products in a total of 61 dosage strengths.

In addition to those products that we manufacture in the U.S., we also market, principally through UDL, 50 generic products in a total of 102 dosage strengths under supply and distribution agreements with other pharmaceutical companies. We believe that the breadth of our product offerings helps us to successfully meet our customers needs and to better compete in the generic industry over the long term.

Our U.S. product portfolio also includes three transdermal patch products in a total of 15 dosage strengths that are developed and manufactured by MTI. 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.

We believe the future growth of our U.S. generics business is partially dependent upon continued increasing acceptance of generic products as low cost alternatives to branded pharmaceuticals, a trend which is largely out 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 ten years, in addition to fentanyl, we have successfully introduced generic products with high barriers to entry, including our launches of, among others, levetiracetam, divalproex, extended phenytoin sodium, levothyroxine sodium, oxybutynin, paroxetine and lansoprazole. Several of these products continued to be meaningful contributors to our business several years after their initial launch, due to their high barriers to entry. Additionally, we expect to achieve growth in our

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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.

Through Mylan Pharmaceuticals ULC, our wholly-owned subsidiary, we manufacture and market generic pharmaceuticals in Canada, the world s third largest generic retail prescription market with revenues of $4.3 billion for the twelve months ended November 2009. Mylan Pharmaceuticals ULC offers a portfolio of approximately 120 products, in an aggregate of approximately 260 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 increased acceptance of generic products as low cost alternatives to branded pharmaceuticals. Further, we hope 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. We have operations in 25 countries. Of the top ten generic retail pharmaceutical markets in Europe, we hold a number one market share position in France and Italy, we hold a top three market share position in the United Kingdom (U.K.), Belgium and Portugal, and we hold a top five market share position in Spain and the Netherlands.

Within EMEA, we characterize the different markets in which we operate as growth, commodity or emerging, based on the size, maturity and expected growth rates of each market. We consider our growth markets to include France, Italy, Spain, Portugal and Belgium. We consider our commodity markets to include Germany, the U.K. and the Netherlands. Finally, we consider our emerging markets to include several markets in Central and Eastern Europe.

In France, we market through our subsidiaries, Mylan S.A.S. and Qualimed S.A.S., a portfolio of approximately 160 products, in an aggregate of approximately 310 dosage strengths. France has the second largest generic retail pharmaceutical market in Europe with sales of approximately $4.07 billion during the twelve months ended November 2009. We hold the number one market share position in the company branded generic retail prescription market, as measured by value, with a share of approximately 31%. Future growth in the French market is expected to come from new product launches and an increase in generic substitution.

In Italy, we market through our subsidiary, Mylan S.p.A., a portfolio of approximately 110 products, in an aggregate of approximately 210 dosage strengths. The generic retail prescription market in Italy is the fourth largest generic market in Europe, with sales of approximately $2.25 billion during the twelve months ended November 2009. In Italy, we are the number one ranked company in terms of market share in the company branded generic retail prescription market, based on value. The Italian generics market emphasizes brand quality and the importance of being first-to-market in order to capture and maintain market share. We believe that the Italian generic market is underpenetrated, with generics representing approximately 17% 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 off-patent molecules.

In Spain, we market through our subsidiary, Mylan Pharmaceuticals S.L., a portfolio of approximately 80 products, in an aggregate of approximately 190 dosage strengths. The generic retail prescription market in Spain is the fifth largest generic market in Europe, with sales of approximately $2.04 billion during the twelve months ended November 2009. We are the fifth ranked company in Spain in terms of market share in the company branded generic retail prescription market, based on value. Similar to Italy, the Spanish generics market is focused on brand quality and service level (reliable supply and customer orientation), and it is important to be first-to-market in order to capture market share. The generic market made up approximately 15% of the total Spanish retail pharmaceutical market by sales for the

twelve months ended November 2009. We view further generic penetration of the Spanish market to be a key driver of our growth in that nation.

In Germany, we market through our subsidiary, Mylan dura, a portfolio of approximately 160 products, in an aggregate of approximately 830 dosage strengths. The German generic retail prescription market is the largest

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generic market in Europe, with sales of approximately $6.10 billion during the twelve months ended November 2009. As of November 2009, Mylan dura ranked number seven in terms of market share in the company branded generic retail prescription market in Germany, based on value. Most generic products in Germany are sold as brands, and health insurance companies are starting to play a major role as tenders are implemented. As a result of these tenders, our business in Germany has declined. Future growth in the German marketplace will depend upon our ability to compete based primarily on price.

In the U.K., we offer a broad product portfolio of approximately 170 products, in an aggregate of approximately 380 dosage strengths. The U.K. generic retail prescription market is the third largest market in Europe, with sales of approximately $2.94 billion for the twelve months ended November 2009. As of November 2009, Mylan ranked third in the U.K. reimbursement market, in terms of value, with an estimated market share of 11%. Mylan in the U.K. is well positioned as a preferred supplier to wholesalers and is also focused on areas such as multiple retail pharmacies and hospitals. The U.K. generics market is highly competitive, and any growth in the market will stem from new product launches, although the value will continue to be effected by price erosion.

We also have a notable presence in several other European markets, including Sweden, where we hold a top three ranking in terms of value in the company branded generic retail prescription market, and Ireland, where we hold a top five market position in terms of value in the generic retail prescription market. 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, 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 wholly-owned subsidiaries in Australia, New Zealand, India and Japan. Additionally, we market API to third parties as well as to other Mylan subsidiaries through our Indian subsidiary, Matrix. We hold the number one market positions in both Australia and New Zealand and the number four market position in Japan.

The generic pharmaceutical market in Australia had sales of approximately $750.0 million during the twelve months ended December 2009. Alphapharm, our Australian subsidiary, is the largest supplier by volume of prescription pharmaceuticals in Australia. It is also the generics market leader in Australia, holding an estimated 60% market share by volume as of December 2009, and offering the largest portfolio of generic pharmaceutical products in the Australian market with approximately 160 products, in an aggregate of approximately 350 dosage strengths. The generics market in Australia is still underdeveloped, and as a result, the government is increasingly focused on promoting generics in an effort to reduce costs. Maintaining our position of market leadership as the market undergoes further generic penetration will be the key to our future success in Australia. In New Zealand, our business operates under the name Mylan New Zealand and is the largest generics company in the country.

Mylan Seiyaku, our Japanese subsidiary, offers a broad portfolio of approximately 470 products, in an aggregate of approximately 830 dosage strengths. We have a manufacturing 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 seventh largest generic retail prescription market worldwide, with sales of approximately $3.70 billion during the twelve months ended November 2009. The market is currently mostly hospitals, but is expected to move into pharmacies as generic substitution becomes more prevalent. Recent pro-generics government actions include fixed hospital reimbursement for certain procedures, and pharmacy substitution. Japan is trying to grow generic utilization to 30% by 2012. These actions are expected to be key drivers of our future growth and profitability in Japan, which we see as our primary growth driver in Asia Pacific.

In India, we conduct our business through Matrix, of which its finished dosage business produces mostly ARV products which are sold outside of India. Expansion of this line, and an increase in domestic sales, are both key drivers of future growth.

In addition, Asia Pacific revenues are augmented by sales of API, of which Matrix is one of the world s largest manufacturers with respect to the number of DMFs filed with regulatory agencies. Mylan currently has more than

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200 APIs in the market or under development, and focuses its marketing efforts on regulated markets such as the U.S. and the European Union (EU). We produce API for use in the manufacture of Mylan s 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. Matrix is also a leading supplier of generic ARV APIs used in the treatment of HIV.

Matrix has eight API and intermediate manufacturing facilities and one FDF facility. Two of the API and intermediate manufacturing facilities are located in China. Six of the facilities, including the FDF facility, are FDA approved, making Matrix 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 horizontally and 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 products are primarily branded specialty nebulized, injectable and transdermal products for life-threatening conditions. Since our acquisition of Dey, a significant portion of Dey s revenues have been derived primarily through the sale of the EpiPen® auto-injector.

The EpiPen auto-injector, which is used in the treatment of severe allergies, is an epinephrine auto-injector which has been sold in the U.S. since 1980 and internationally since the mid-1980 s. Dey has world-wide rights to the epinephrine auto-injector supplied to Dey by Meridian Medical Technologies and a world-wide license to the EpiPen trademark from Mylan. The EpiPen auto-injector is the number one prescribed auto-injector with world-wide market share of 93% and U.S. market share of 96%. 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. Also, on October 1, 2009, Dey launched a new design of the epinephrine auto-injector in the U.S., which provides enhanced user-friendly attributes to the pen, further allowing Dey to maintain its strong leadership position in the severe allergy market.

Perforomist® Solution, Dey s formoterol fumarate inhalation solution, was launched on October 2, 2007. Perforomist Solution is a long-acting beta2-adrenergic agonist indicated for long-term, twice-daily administration in the maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disease patients, including those with chronic bronchitis and emphysema. Dey has been issued several U.S. and international patents protecting Perforomist Solution.

We believe we can continue to drive the long-term growth of our Specialty Segment by successfully managing our existing product portfolio, growing our newly launched products 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 generally provides brand products with the ability to maintain their profitability for relatively long periods of time. Brand products generally continue to have a significant role in the market after the end of patent protection or other market exclusivities due to physician and consumer loyalties.

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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 and the expiration, invalidation or circumvention of any patents on the corresponding brand drug, or the end of any other market exclusivity periods related to the brand drug. Generic drugs are bioequivalent to their brand name counterparts. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these 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. New generic product approvals are obtained from the FDA through the ANDA process, which requires us to demonstrate bioequivalence to a reference brand product. 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 New Drug Application (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 the same generic equivalent.

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:

NDA. A NDA is filed when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. NDAs are filed for newly developed branded products and, in certain instances, for a new dosage form, a new delivery system, or a new indication for previously approved drugs.

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.

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.

FDA approval of an ANDA is required before marketing a generic equivalent of a drug approved under an NDA in the U.S. or for a previously unapproved dosage strength or delivery system for a drug approved under an ANDA. The ANDA development process is generally less time-consuming and complex than the NDA

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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 drug previously approved through the NDA process. The ANDA process, however, does require one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved drug. Bioequivalence compares the bioavailability of one drug product with that of another formulation containing the same active ingredient. When established, bioequivalence confirms that the rate of absorption and levels of concentration in the bloodstream of a formulation of the previously approved drug and the generic drug are equivalent. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the bloodstream needed to produce the same therapeutic effect.

Additionally, any ANDA seeking approval of a generic equivalent version of a referenced brand drug before expiration of the referenced patent(s) must include a certification to the FDA either that the listed patent is not infringed or that it is invalid or unenforceable (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, the expiration of 30 months, or the expiration of the patent.

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 bioequivalent product. If the listed drug is a new chemical entity, the FDA may not accept an ANDA for a bioequivalent 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 a bioequivalent product before the expiration of three years. Certain other periods of exclusivity may be available if the listed 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.

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to rebate a percentage of their revenues arising from Medicaid-reimbursed drug sales to individual state Medicaid agencies. The required rebate is currently 11% of the average manufacturer s price for sales of Medicaid-reimbursed products marketed under ANDAs. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 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, a trend which 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.

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 FDA requires that the manufacturing operations of both API and FDF manufacturers, regardless of where in the world they are located, comply with cGMP.

In Canada, the registration process for approval of all generic pharmaceuticals has two tracks which proceed in parallel. The first track is concerned with the quality, safety and efficacy of the proposed generic product, and the

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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 a 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 first track of the process involves an examination of the ANDS by Health Canada to ensure that the quality, safety and efficacy of the product meet Canadian standards and bioequivalence.

The second track of the approval process is governed by the Patented Medicines NOC Regulations (Regulations). The owner or exclusive licensee, or originator, of patents relating to the brand drug for which it has a 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 a 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. A NOC can be obtained for a generic product only if the applicant is successful in defending 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 a NOC was issued on or after June 17, 2006. A subsequent applicant for approval to market a drug for which a 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 a 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 a 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 Drug Benefit Formularies. Eligible recipients include seniors, persons on social assistance, low-income earners, and those with certain specified

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conditions or diseases. To be considered for listing in a provincial or territorial Formulary, drug products must have been issued a NOC and must 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 new 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.

In Europe, 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. Legal requirements 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 (CMD) and

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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 pre-clinical 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.

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 the Company 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 unfavorability 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

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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, a 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

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. The Australian government also regulates the quality, safety and efficacy of therapeutic goods.

The government exerts a significant degree of control over the pharmaceuticals market through the Pharmaceutical Benefits Scheme (PBS), which is a governmental program for subsidizing the cost of pharmaceuticals to Australian consumers. Over 80% of all prescription medicines sold in Australia are reimbursed by the PBS. The PBS is operated under the National Health Act 1953 (Cth). This act governs such matters as who may sell pharmaceutical products, the prices at which pharmaceutical products may be sold and governmental subsidies.

For pharmaceutical products listed on the PBS, the price is determined through negotiations between the Pharmaceutical Benefits Pricing Authority (a governmental agency) and pharmaceutical suppliers. 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 caps 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 or margins. There were changes in 2008 to the pricing regime for PBS-listed medicines, which have decreased the margin wholesalers can realize. However, the Australian government has established a fund to compensate wholesalers under certain circumstances for the impact on the wholesale margin resulting from the new pricing arrangements.

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

Manufacturers and suppliers of pharmaceutical products are also regulated by the Therapeutic Goods Administration (TGA), which administers the Therapeutic Goods Act 1989 (Cth) (Act). The Act regulates the quality, safety and efficacy of 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.

All therapeutic goods manufactured for supply in Australia must be listed or registered in the Australian Register of Therapeutic Goods (ARTG), before they can be supplied. 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

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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.

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 (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 Minister 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 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 Minister, 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 Minister 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 Minister can order the cancellation or amendment of a Marketing Approval when (1) the necessary materials for re-examination or re-evaluation, which the Minister 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

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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.

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

Specialty Segment

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

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

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

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

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

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

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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.

All pharmaceutical manufacturers are subject to extensive, complex and evolving regulation by the federal government, principally the FDA and, to a lesser extent, other federal and state government agencies. The Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act, the Hatch-Waxman Act, the Generic Drug Enforcement Act, and other federal government statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storage, recordkeeping, safety, approval, advertising, promotion, sale and distribution of products.

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug that is the subject of the application. Upon NDA approval, the FDA lists the approved drug product and these patents in the Orange Book. Any applicant that files an ANDA seeking approval of a generic equivalent version of a referenced brand drug before expiration of the referenced patent(s) must certify to the FDA either that the listed patent is not infringed or that it is invalid or unenforceable (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.

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 bioequivalent product. If the listed drug is a new chemical entity, the FDA may not accept an ANDA for a bioequivalent 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 a bioequivalent product before the expiration of three years. Certain other periods of exclusivity may be available if the listed drug is indicated for treatment of a rare disease or is studied for pediatric indications.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the 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 good manufacturing practices in the U.S. and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

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. With the acquisitions of Matrix and the former Merck Generics business, we have significantly bolstered our global research and development capabilities. 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 Agency Francaise de Securite Sanitaire des Produicts 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 fur 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;

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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 unit dose oral inhalation products for nebulization;

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;

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.

During the year ended December 31, 2009, we received 593 product approvals globally. Of that total, 43 were in the U.S., six in Canada, 45 in Asia Pacific, 386 in EMEA, nine from the WHO and 104 approvals for ARV products. The 43 approvals in the U.S. consisted of 26 final ANDA approvals and 17 tentative ANDA approvals.

The 104 approvals of ARV products were received from the U.S. President s Emergency Plan for AIDS Relief (PEPFAR) and the WHO and consisted of 18 different products in 17 countries. During 2009, we made tremendous strides in developing more affordable ARV products, including WHO approval of the first heat-stable ARV tablet, Lopinavir/Ritonavir, for which we received WHO approval.

We have a robust generic pipeline. During 2009, we completed 905 submissions globally, which included 91 in North America, 649 in EMEA and 165 in Asia Pacific. These submissions included those for existing products in new markets as well as products new to the Mylan portfolio.

As of December 31, 2009, we had 142 ANDAs pending FDA approval, representing $87.5 billion in annual sales for the brand name equivalents of these products for the twelve months ended June 30, 2009. Of those pending product applications, 41 were first-to-file Paragraph IV ANDA patent challenges, representing $19.6 billion in annual brand sales for the twelve months ended June 30, 2009.

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.

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A 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 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 the Company currently estimates 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, 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

Dey markets its products to a number of different customer audiences in the U.S., including health care practitioners, wholesalers, pharmacists and pharmacy chains, home health care and long-term care. We reach these customers through our field-based sales force of approximately 260 employees, to increase our customers understanding of the unique clinical characteristics and benefits of our branded products.

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

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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.

During 2009, sales to McKesson Corporation and Cardinal Health, Inc. represented 10% each of consolidated net revenues. During 2008, sales to McKesson Corporation and Cardinal Health, Inc. represented 12% and 10% of consolidated net revenues. Sales to McKesson Corporation and Cardinal Health, Inc. represented 16% and 11% of consolidated net revenues during the nine months ended December 31, 2007.

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.

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, customer service, reputation and price. To compete effectively on the basis of price and remain profitable, a generic drug manufacturer must manufacture its products in a cost-effective manner.

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. No further regulatory approvals are 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.

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.

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

Italy. The Italian generic market is relatively small due to few incentives for market stakeholders, and in part to low prices on available brand-name drugs. Also to be considered is the fact that the generic market in Italy suffered a

certain delay compared to other European countries due to extended patent protection. The Italian government has put forth only limited measures aimed at increasing generic usage; generic substitution is still in its early stages.

Spain. Spain is a rapidly growing, highly fragmented generic market with many participants. Certain regions permit generic substitution by pharmacists, while others do not. As such, physicians and/or pharmacists are the key

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drivers of generic usage depending upon the region. Companies compete in Spain based on name recognition, service level and 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 most recently a move toward 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. The Japanese generic market is small by international standards. 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, availability of highly skilled labor and the low-cost manufacturing base.

Product Liability

Product liability litigation represents an inherent risk to firms in the pharmaceutical industry. Our 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 insurance coverage or to self-insure varies accordingly.

We utilize a combination of self-insurance (through our wholly-owned captive insurance subsidiary) and traditional third-party insurance policies to cover product liability claims. We are self-insured for the first $15.0 million of costs incurred relating to product liability claims and maintain third-party insurance that provides, subject to specified co-insurance requirements, significant coverage limits in excess of our initial self-insured layer. Furthermore, outside of the U.S., we purchased a commercial insurance policy in each country that complies with the local country insurance laws and is reinsured to our wholly-owned captive insurance subsidiary. Additionally, certain subsidiaries in highly regulated countries maintain commercial coverage up to $15.0 million with minimal retentions.

Raw Materials

Mylan utilizes a global approach to managing relationships with its suppliers. Matrix provides Mylan with significant vertical integration opportunities that have been significantly enhanced with the purchase of the former Merck Generics business. The APIs and other materials and supplies used in our pharmaceutical manufacturing operations are generally available and purchased from many different domestic and foreign suppliers, including Matrix. 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

We currently employ more than 15,500 people globally, made up of approximately 12,500 permanent employees and approximately 3,000 temporary employees. The production and maintenance employees at our manufacturing facility in Morgantown, West Virginia, are represented by the United Steelworkers of America (USW) (AFL-CIO) and its Local Union 957 AFL-CIO under a contract that expires on April 15, 2012. In addition, there are non-U.S. Mylan locations, primarily concentrated in Europe and India, that have employees who are unionized or part of works councils or trade unions.

Securities Exchange Act Reports

The Company maintains an Internet website at the following address: www.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, N.E., 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.

The global economy has undergone a period of unprecedented volatility, and the economic environment may continue to be less favorable than that of past years. This has led, and could further lead, to reduced consumer spending in the foreseeable future, and this may include spending on healthcare. While generic drugs present an ideal alternative to higher-priced branded products, our sales could be negatively impacted if patients forego obtaining healthcare. In addition, reduced consumer spending may drive us and our competitors to decrease prices. These conditions may adversely affect 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 CONTINUING INTEGRATION OF THE FORMER MERCK GENERICS BUSINESS 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.

We acquired the former Merck Generics business in October 2007. There continue to be a number of operational risks associated with the acquisition and related integration, including but not limited to:

- difficulties in successfully integrating the operations and personnel of the former Merck Generics business with our historical business and corporate culture;
- difficulties in achieving identified financial and operating synergies;
- diversion of management s attention from our ongoing business concerns to integration matters;
- the potential loss of key personnel or customers;
- difficulties in consolidating information technology platforms, business applications and corporate infrastructure;
- our substantial indebtedness and assumed liabilities;
- the incurrence of significant additional capital expenditures, operating expenses and non-recurring acquisition-related charges;
- challenges in operating in other markets outside of the U.S. that are new to us; and
- 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 MAY FAIL TO REALIZE THE EXPECTED COST SAVINGS, GROWTH OPPORTUNITIES AND OTHER BENEFITS ANTICIPATED FROM THE ACQUISITIONS OF THE FORMER MERCK GENERICS BUSINESS AND MATRIX, 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 success of the acquisitions of the former Merck Generics business and Matrix will depend, in part, on our ability to realize anticipated cost savings, revenue synergies and growth opportunities from integrating the businesses. We expect to benefit from operational cost savings resulting from the consolidation of capabilities and elimination of redundancies as well as greater efficiencies from increased scale and market integration.

There is a risk, however, that the businesses may not be combined in a manner that permits these costs savings or synergies to be realized in the time currently expected, or at all. This may limit or delay our ability to integrate the companies manufacturing, research and development, marketing, organizations, procedures, policies and operations. In addition, a variety of factors, including, but not limited to, wage inflation and currency fluctuations, may adversely

affect our anticipated cost savings and revenues.

Also, we may be unable to achieve our anticipated cost savings and synergies without adversely affecting our revenues. If we are not able to successfully achieve these objectives, the anticipated benefits of these acquisitions may not be realized fully, or at all, or may take longer to realize than expected. 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.

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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 and Matrix. 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. 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;

changes in laws, regulations, and practices affecting the pharmaceutical industry and the healthcare system, including but not limited to imports, exports, manufacturing, cost, pricing, reimbursement, approval, inspection, and delivery of healthcare;

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. Certain 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.

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 a significant extent, upon our ability to successfully develop and/or license, or otherwise acquire and commercialize, new generic and patent or statutorily protected

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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 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 Food and Drug Administration (FDA) in the U.S. and the European Medicines Agency (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. Bioequivalency 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 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. 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 relevant patents when the core patent expires, for example, new formulations, the owner of the original brand pharmaceutical may be able to obtain preliminary injunctions in certain European jurisdictions preventing launch of the generic product, if the generic

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company did not commence proceedings in a timely manner to invalidate any relevant patents prior to launch of its generic.

In addition, in jurisdictions other than 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.

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 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.

The current U.S. presidential administration recently reintroduced, in somewhat modified form, several proposals to change U.S. income tax rules, including proposals for U.S. international tax reform. The proposals would, among other things, limit the use of foreign tax credits to reduce residual U.S. income tax on non-U.S. source income and defer the deduction of interest attributable to non-U.S. source income of foreign subsidiaries. Each of these proposals would be effective only for taxable years beginning after December 31, 2010. We cannot determine whether these

proposals will be enacted into law or what, if any, changes will be made to such proposals prior to their being enacted into law. 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.

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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.

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.

A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR NET 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 often represent a significant portion of our net revenues, gross profit and net earnings. 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.

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.

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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.

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, 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 manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with regulations of the FDA and other regulators can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, 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, there is no guarantee that these programs, as currently designed, will meet regulatory agency standards in the future. Additionally, despite our efforts at compliance, there is 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, 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 at one of our manufacturing facilities could result in an enforcement action brought by the FDA or other regulatory bodies which could include withholding the approval of our submissions or other product applications of that facility. If any regulatory body were to 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 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. We are also required to comply with data protection and data privacy rules in many countries. Although we have not incurred significant costs associated with complying with 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 controls, 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.

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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 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. Further, effective October 1, 2007, the Centers for Medicaid and Medicare Services, or CMS, adopted new rules for Average Manufacturer s Price (AMP) based on the provisions of the Deficit Reduction Act of 2005 (DRA). While the matter remains subject to litigation and proposed legislation, one potential significant change as a result of the DRA is that AMP would need to be disclosed to the public. AMP was historically kept confidential by the government and participants in the Medicaid program. Disclosing AMP to competitors, 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 the Company could 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 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. 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 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

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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 request that we conduct additional studies and, as a result, we may be unable to reasonably determine the total research and development costs to develop a particular product. 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.

A SIGNIFICANT PORTION OF OUR NET REVENUES IS 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 net revenues is derived from sales to a limited number of customers. If we were to experience a significant reduction in or loss of business with one 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.

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.

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;
- 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.

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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.

WE HAVE SUBSTANTIAL INDEBTEDNESS AND WILL BE REQUIRED TO APPLY A SUBSTANTIAL PORTION OF OUR CASH FLOW FROM OPERATIONS TO SERVICE OUR INDEBTEDNESS. 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.

We incurred significant indebtedness to fund a portion of the consideration for our acquisition of the former Merck Generics business. Our high 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 and proceeds of any equity issuances to payments on our indebtedness, thereby reducing the availability of cash flow to fund working capital, capital expenditures, acquisitions and investments and other general corporate purposes;
- making it difficult for us to optimally capitalize and manage the cash flow for our businesses;
- limiting our flexibility in planning for, or reacting to, changes in our businesses and the markets in which we operate;
- making it difficult for us to meet the leverage and interest coverage ratios required by our Senior Credit Agreement;
- limiting our ability to borrow money or sell stock 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;
- requiring us to sell assets in order to pay down debt; and
- placing us at a competitive disadvantage to our competitors that have less debt.

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 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. Furthermore, the global credit markets are currently experiencing an unprecedented contraction. If current pressures on credit continue or worsen, 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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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. We also continue to review the carrying value of manufacturing and intangible assets for indications of impairment as circumstances require. Future events and decisions may lead to asset impairments and/or related costs. As a result, any such sale or impairment 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.

OUR CREDIT FACILITIES AND ANY ADDITIONAL INDEBTEDNESS WE INCUR IN THE FUTURE IMPOSE, OR MAY IMPOSE, SIGNIFICANT OPERATING AND FINANCIAL RESTRICTIONS, WHICH MAY PREVENT US FROM CAPITALIZING ON BUSINESS OPPORTUNITIES. 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.

Our credit facilities 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.

WE DEPEND 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. A PROLONGED 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. A prolonged 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.

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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 Drug Enforcement Administration (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.

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 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 dependant on market perceptions, negative publicity associated with illness or other adverse effects 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.

WE HAVE A LIMITED NUMBER OF MANUFACTURING FACILITIES PRODUCING A SUBSTANTIAL PORTION OF OUR PRODUCTS. PRODUCTION AT ANY ONE OF THESE FACILITIES COULD BE INTERRUPTED, 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.

A substantial portion of our capacity as well as our current production is attributable to a limited number of manufacturing facilities. A significant disruption at any one of those facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, 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 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.

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

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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.

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 the Company uses its business judgment and decides 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 situation). 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 trebled. 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 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.

WE MAY EXPERIENCE REDUCTIONS IN THE LEVELS OF REIMBURSEMENT FOR PHARMACEUTICAL PRODUCTS BY GOVERNMENTAL AUTHORITIES, HMOS OR OTHER THIRD-PARTY PAYERS. 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 reimbursement 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 payers 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 (including, most recently, the Netherlands) 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

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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.

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.

On July 18, 2008, the Australian government mandated a 25% price reduction on generic pharmaceutical products sold in Australia. Such a widespread price reduction of this magnitude is unprecedented in Australia. As a result, pharmaceutical companies have generally experienced significant declines in revenues and profitability and uncertainties continue to exist within the market. This price reduction has had an adverse effect on our business in Australia, and as uncertainties are resolved or if other countries in which we operate enact similar measures, they could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

HEALTHCARE 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 healthcare 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. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including the provision of comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. The ultimate content or timing of any future health reform legislation, and its impact on us, is impossible to predict.

While health care reform may increase the number of patients who have insurance coverage for our products, Congress has also considered legislation to change the Medicare reimbursement system for outpatient drugs, to add a subsidy for certain out-of-pocket patient costs under Medicare Part D, to assess a pharmaceutical manufacturer fee, to

increase the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs and to facilitate the importation of lower-cost prescription drugs that are marketed outside the U.S.

Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid.

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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 reforms are made to the U.S. healthcare system, or to the healthcare systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial 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.

We are involved in various legal proceedings and certain government inquiries, including, but not limited to, patent infringement, product liability, breach of contract and claims involving Medicare and/or Medicaid reimbursements, 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. 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 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 and/or subject to investigation 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.

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.

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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.

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.

We may be unable to realize synergies or other benefits 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 a 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. 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.

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MATRIX, AN IMPORTANT PART OF OUR BUSINESS, IS LOCATED IN INDIA AND IT IS SUBJECT TO REGULATORY, ECONOMIC, SOCIAL AND POLITICAL UNCERTAINTIES IN INDIA. 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.

In recent years, Matrix 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 healthcare and education. Our ability to recruit, train and retain qualified employees and develop and operate our manufacturing facilities in India could be adversely affected if India does not successfully meet these challenges.

Southern Asia has, from time to time, experienced instances of civil unrest and hostilities among neighboring countries, including India and Pakistan, and within the countries themselves. Rioting, military activity or terrorist attacks in the future could influence the Indian economy by disrupting communications and making travel 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 Matrix 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, Matrix 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 our costs are denominated in foreign currencies, including the Australian Dollar, the British Pound, the Canadian Dollar, the Euro, 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, could be adversely affected by certain movements in exchange rates. 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 payments 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.

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,

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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 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. 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 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 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.

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

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

Effective internal controls are necessary for the Company to provide reasonable assurance with respect to its financial reports. We are spending a substantial amount of management time and resources to comply with changing laws, regulations and standards relating to corporate governance and public disclosure. In the U.S. such changes 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 attestations 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 the Company fails to maintain the adequacy of its 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.

THE TOTAL AMOUNT OF INDEBTEDNESS RELATED TO OUR OUTSTANDING CASH CONVERTIBLE NOTES WILL INCREASE IF OUR STOCK PRICE INCREASES. IN ADDITION, OUR OUTSTANDING SENIOR NOTES SETTLEMENT VALUE INCREASES AS OUR STOCK PRICE INCREASES, ALTHOUGH WE DO NOT ACCOUNT FOR THIS AS AN INCREASE IN INDEBTEDNESS. ALSO, WE HAVE ENTERED INTO NOTE HEDGES AND WARRANT TRANSACTIONS IN CONNECTION WITH THE SENIOR CONVERTIBLE NOTES AND 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 our existing and any future debt agreements. For example, our senior credit facilities contain covenants that restrict our ability to incur debt, make capital expenditures, pay dividends and make investments if, among other things, our leverage ratio, exceeds certain levels. In addition, the interest rate we pay under our senior credit facilities increases if our leverage ratio increases. Because the leverage ratio under our senior credit facilities is calculated based on a definition of total indebtedness as defined under accounting principles generally accepted in the United States of America (GAAP), if the amount of our total indebtedness were to increase, our leverage ratio would also increase. 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.

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Although the conversion feature under our Senior Convertible Notes is not marked to market, the conversion feature also increases as the price of our common stock increases. If our stock price increases, the settlement value of the conversion feature increases.

In connection with the issuance of the Cash Convertible Notes and Senior 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. The Senior Convertible Notes hedge is comprised of call options that are expected to reduce our exposure to the settlement value (issuance of common stock) upon the 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.

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 (including intangible 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 lawsuits based on estimates of probable future costs, such lawsuits 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 assets (including goodwill and other intangible assets), 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.

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.

The U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or

retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We operate in jurisdictions that have experienced governmental 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

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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.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

We maintain various facilities that are used for manufacturing, research and development, warehousing, distribution and administrative functions. These facilities consist of both owned and leased properties.

The following summarizes the significant properties used to conduct our operations:

Primary Segment	Location	Status	Primary Use
Generics Segment	North Carolina	Owned	Warehousing, Distribution
	West Virginia	Owned	Manufacturing, R&D, Warehousing, Administrative
	Illinois	Owned	Manufacturing, Warehousing, Administrative
	Texas	Owned	Manufacturing, Warehousing
	Vermont	Owned	Manufacturing, Warehousing, Administrative
	Puerto Rico	Owned	Manufacturing, Warehousing, Administrative
	Germany	Leased	Administrative, Warehousing
	France	Owned	Manufacturing
		Leased	Administrative
	United Kingdom	Owned	Administrative
		Leased	Warehousing, Administrative
	Ireland	Owned	Manufacturing, Warehousing, Distribution, Administrative
		Leased	Warehousing
	Australia	Owned	Manufacturing, Warehousing, Distribution, Administrative
		Leased	Manufacturing, Warehousing, Administrative
	Netherlands	Leased	Warehousing, Distribution, Administrative
	Belgium	Leased	Warehousing, Administrative
	Canada	Owned	Manufacturing, Warehousing, Distribution, Administrative
		Leased	Warehousing, Distribution
	India	Owned	Manufacturing, R&D, Warehousing, Distribution, Administrative
		Leased	R&D, Administrative
	Japan	Owned	

			Manufacturing, Administrative, Warehousing
		Leased	Warehousing, Administrative
	China	Owned	Manufacturing, Warehousing, Administrative
		Leased	Manufacturing
Specialty Segment	California	Owned	Manufacturing, Warehousing, Distribution, Administrative
	New Jersey	Leased	Administrative

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Primary Segment	Location	Status	Primary Use
	Texas	Leased	Warehousing, Distribution
Corporate/Other	Pennsylvania	Owned	Administrative
	New York	Leased	Administrative

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 current operations.

ITEM 3. Legal Proceedings

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. The Company is also party to certain litigation matters, some of which are described below, for which Merck KGaA has agreed to indemnify the Company, under the terms of the Share Purchase Agreement by which Mylan acquired the former Merck Generics business. An adverse outcome in any of these proceedings, or the inability or denial of Merck KGaA to pay an indemnified claim, could have a material adverse effect on the Company s financial position and results of operations and cash flows.

Lorazepam and Clorazepate

On June 1, 2005, a jury verdict was rendered against Mylan, Mylan Pharmaceuticals Inc. (MPI), and co-defendants Cambrex Corporation and Gyma Laboratories in the U.S. District Court for the District of Columbia in the amount of approximately $12.0 million, which has been accrued for by the Company. The jury found that Mylan and its co-defendants willfully violated Massachusetts, Minnesota and Illinois state antitrust laws in connection with API supply agreements entered into between the Company and its API supplier (Cambrex) and broker (Gyma) for two drugs, lorazepam and clorazepate, in 1997, and subsequent price increases on these drugs in 1998. The case was brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001 and represents the last remaining antitrust claims relating to Mylan s 1998 price increases for lorazepam and clorazepate. Following the verdict, the Company filed a motion for judgment as a matter of law, a motion for a new trial, a motion to dismiss two of the insurers and a motion to reduce the verdict. On December 20, 2006, the Company s motion for judgment as a matter of law and motion for a new trial were denied and the remaining motions were denied on January 24, 2008. In post-trial filings, the plaintiffs requested that the verdict be trebled and that request was granted on January 24, 2008. On February 6, 2008, a judgment was issued against Mylan and its co-defendants in the total amount of approximately $69.0 million, which, in the case of three of the plaintiffs, reflects trebling of the compensatory damages in the original verdict (approximately $11 million in total) and, in the case of the fourth plaintiff, reflects their amount of the compensatory damages in the original jury verdict plus doubling this compensatory damage award as punitive damages assessed against each of the defendants (approximately $58 million in total), some or all of which may be subject to indemnification obligations by Mylan. Plaintiffs are also seeking an award of attorneys fees and litigation costs in unspecified amounts and prejudgment interest of approximately $8.0 million. The Company and its co-defendants have appealed to the U.S. Court of Appeals for the D.C. Circuit and intend to challenge the verdict as legally erroneous on multiple grounds. The appeals were held in abeyance pending a ruling on the motion for prejudgment interest, which has been granted. Mylan intends to contest this ruling along with the liability finding and other damages awards as part of its pending appeal, which is proceeding in the Court of Appeals for the D.C. Circuit. In connection with the Company s appeal of the lorazepam judgment, the Company submitted a surety bond underwritten by a third-party insurance company in the amount of $74.5 million. This surety bond is secured by a pledge of a $40.0 million cash deposit (which is included as restricted cash on the Company s Consolidated Balance Sheet as of December 31, 2009) and an irrevocable letter of credit for $34.5 million issued

under the Senior Credit Agreement.

Pricing and Medicaid Litigation

Beginning in September 2003, Mylan, MPI and/or UDL Laboratories Inc. (UDL), together with many other pharmaceutical companies, have been named in civil lawsuits filed by state attorneys general (AGs) and

municipal bodies within the state of New York alleging generally that the defendants defrauded the state Medicaid systems by allegedly reporting Average Wholesale Prices and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants prescription drugs, causing state programs to overpay pharmacies and other providers. To date, Mylan, MPI and/or UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, Alaska, California, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Massachusetts, Mississippi, Missouri, South Carolina, Texas, Utah and Wisconsin and also by the city of New York and approximately 40 counties across New York State. Several of these cases have been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. Others of these cases will likely be litigated in the state courts in which they were filed. Each of the cases seeks money damages, civil penalties and/or double, treble or punitive damages, counsel fees and costs, equitable relief and/or injunctive relief. Certain of these cases may go to trial in 2010. Mylan and its subsidiaries have denied liability and intend to defend each of these actions vigorously. On January 27, 2010, in the New York Counties cases, the United States District Court for the District of Massachusetts granted Plaintiffs motion for partial summary judgment as to liability under New York Social Services Law § 145-b against Mylan and several other defendants. The District Court has not ruled on the remaining issues of liability and damages. On February 8, 2010, Mylan, and a majority of the other defendants, filed a motion to amend the Court s decision, requesting the Court to certify a question of New York state law pertaining to the court s finding of requisite causation under the Social Services Law to the First Circuit Court of Appeals, so that the defendants could in turn request that the First Circuit Court of Appeals certify the question to the New York Court of Appeals.

In May 2008, an amended complaint was filed in the U.S. District Court for the District of Massachusetts by a private plaintiff on behalf of the United States of America, against Mylan, MPI, UDL and several other generic manufacturers. The original complaint was filed under seal in April 2000, and Mylan, MPI and UDL were added as parties in February 2001. The claims against Mylan, MPI, UDL and the other generic manufacturers were severed from the April 2000 complaint (which remains under seal) as a result of the federal government s decision not to intervene in the action as to those defendants. The complaint alleges violations of the False Claims Act and sets forth allegations substantially similar to those alleged in the state AG cases mentioned in the preceding paragraph and purports to seek nationwide recovery of any and all alleged overpayment of the federal share under the Medicaid program, as well as treble damages and civil penalties. In February 2010, the Company reached an agreement in principle to settle this case (except for the claims related to the California federal share) and the Texas state action mentioned above. This settlement is contingent upon the execution of definitive settlement documents, and federal government and court approval. The settlement would resolve a significant portion of the damages claims asserted against Mylan, MPI and UDL in the various pending pricing litigations. With regard to the remaining state actions, the Company continues to believe that it has meritorious defenses and will continue to vigorously defend itself in those actions. The Company has accrued $160 million in connection with the above-mentioned settlement in principle and the remaining state actions. The Company reviews the status of these actions on an ongoing basis, and from time to time, the Company may settle or otherwise resolve these matters on terms and conditions that management believes are in the best interests of the Company. There are no assurances that settlements can be reached on acceptable terms or that adverse judgments, if any, in the remaining litigation will not exceed the amounts reserved.

In addition, by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning calculations of Medicaid drug rebates. The investigation involved whether MPI and UDL may have violated the False Claims Act by classifying certain authorized generics as non-innovator rather than innovator drugs for purposes of Medicaid and other federal healthcare programs on sales from 2000 through 2004. MPI and UDL denied the government s allegations and denied that they engaged in any wrongful conduct. On October 19, 2009, a lawsuit, filed in March 2004 by a private relator, in which the federal government subsequently intervened, was unsealed by the U.S. District Court for the District of New Hampshire. That same day, MPI and UDL announced that they had entered into a settlement agreement with the federal government, relevant states and the relator for approximately $121.0 million, resolving both the lawsuit and the U.S. Department of Justice investigation. A

stipulation of dismissal with prejudice has been filed with the court. The resolution of the matter did not include any admission or finding of wrongdoing on the part of either MPI or UDL. The Company has recovered approximately $50 million of the settlement amount based on overpayments resulting from adjusted net sales during the relevant timeframe.

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Dey is a defendant currently in lawsuits brought by the state AGs of Arizona, California, Florida, Illinois, Kansas, Kentucky, Pennsylvania and Wisconsin, as well as the city of New York and approximately 40 New York counties. Dey is also named as a defendant in several class actions brought by consumers and third-party payors. Dey has reached a settlement of these class actions, which has been preliminarily approved by the court. Additionally, a complaint was filed under seal by a plaintiff on behalf of the United States of America against Dey in August 1997. In August 2006, the Government filed its complaint-in-intervention and the case was unsealed in September 2006. Dey s motion for partial summary judgment in that case is pending, as is the Government s cross-motion. The Government has asserted that Dey is jointly liable with a codefendant, and seeks recovery of alleged overpayments, together with treble damages, civil penalties and equitable relief. These cases all generally allege that Dey falsely reported certain price information concerning certain drugs marketed by Dey, that Dey caused false claims to be made to Medicaid and to Medicare, and that Dey caused Medicaid and Medicare to make overpayments on those claims. Certain of these cases may go to trial in 2010. Dey intends to defend each of these actions vigorously. The Company has approximately $113.1 million recorded in other liabilities related to the price-related litigation involving Dey. As stated above, in conjunction with the acquisition of the former Merck Generics business, Mylan is entitled to indemnification from Merck KGaA under the Share Purchase Agreement. As a result, the Company has recorded approximately $113.1 million in other assets.

Modafinil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan, along with four other drug manufacturers, has been named as a defendant in civil lawsuits filed in the Eastern District of Pennsylvania and a lawsuit originally filed in Tennessee state court by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafinil and a third-party payor and one action brought by Apotex, Inc., a manufacturer of generic drugs, seeking approval to market a generic modafinil product. These actions allege violations of federal and state laws in connection with the defendants settlement of patent litigation relating to modafinil. These actions are in their preliminary stages, and motions to dismiss each of the Pennsylvania actions are pending. Mylan intends to defend each of these actions vigorously. In addition, by letter dated July 11, 2006, Mylan was notified by the U.S. Federal Trade Commission (FTC) of an investigation relating to the settlement of the modafinil patent litigation. In its letter, the FTC requested certain information from Mylan, MPI and Mylan Technologies, Inc. pertaining to the patent litigation and the settlement thereof. On March 29, 2007, the FTC issued a subpoena, and on April 26, 2007, the FTC issued a civil investigative demand to Mylan requesting additional information from the Company relating to the investigation. Mylan has cooperated fully with the government s investigation and completed all requests for information. On February 13, 2008, the FTC filed a lawsuit against Cephalon in the U.S. District Court for the District of Columbia and the case has subsequently been transferred to the U.S. District Court for the Eastern District of Pennsylvania. Mylan is not named as a defendant in the FTC s lawsuit, although the complaint includes certain allegations pertaining to the Mylan/Cephalon settlement.

Levetiracetam

By letter dated November 19, 2007, Mylan was notified by the FTC of an investigation brought against Mylan and Dr. Reddy s Laboratories, Inc. by UCB Society Anonyme and UCB Pharma, Inc. relating to the settlement in October 2007 of the levetiracetam patent litigation. In its letter, the FTC requested certain information from Mylan pertaining to the litigation and the settlement. On April 9, 2008, the FTC issued a civil investigative demand requesting additional information from Mylan relating to the investigation. Mylan cooperated fully with the government s investigation and complied with all requests for information. By letter dated March 10, 2009, the FTC notified Mylan that it has closed its investigation and that it intends to take no additional action at this time.

Digitek® Recall

On April 25, 2008, Actavis Totowa LLC, a division of Actavis Group, announced a voluntary, nationwide recall of all lots and all strengths of Digitek (digoxin tablets USP). Digitek was manufactured by Actavis and distributed in the United States by MPI and UDL. The Company has tendered its defense and indemnity in all lawsuits and claims arising from this event to Actavis, and Actavis has accepted that tender, subject to a reservation of rights. While the Company is unable to estimate total potential costs with any degree of certainty, such costs could be significant. To date, an estimated 830 lawsuits have been filed against Mylan, UDL and Actavis pertaining

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to the recall. Most of these cases have been transferred to the multi-district litigation proceedings pending in the U.S. District Court for the Southern District of West Virginia for pretrial proceedings. The remainder of these cases will likely be litigated in the state courts in which they were filed. Certain of these cases may go to trial in 2010. An adverse outcome in these lawsuits or the inability or denial of Actavis to pay on an indemnified claim could have a materially negative impact on the Company s financial position and results of operations.

Pioglitazone

On February 21, 2006, a district court in the U.S. District Court for the Southern District of New York held that Mylan, MPI and UDL s pioglitazone abbreviated new drug application (ANDA) product infringed a patent asserted against them by Takeda Pharmaceuticals North America, Inc. and Takeda Chemical Industries, Ltd. (Takeda) and that the patent was enforceable. That same court also held that Alphapharm Pty, Ltd and Genpharm ULC s pioglitazone ANDA product infringed the Takeda patent and that the patent was valid. Subsequently, the district court granted Takeda s motion to find the cases to be exceptional and to award attorneys fees and costs in the amounts of $11.4 million from Mylan and $5.4 million from Alphapharm/Genpharm, with interest, which amounts were paid in 2009. Mylan and Alphapharm/Genpharm both separately appealed the underlying patent validity and enforceability determinations and the exceptional case findings to the Court of Appeals for the Federal Circuit, but the findings were affirmed. Mylan s and Alphapharm s petitions to the U.S. Supreme Court were rejected on October 5, 2009.

EU Commission Proceedings

On or around July 3, 2009, the European Commission (the EU Commission or the Commission) stated that it had initiated antitrust proceedings pursuant to Article 11(6) of Regulation No. 1/2003 and Article 2(1) of Regulation No. 773/2004 to explore possible infringement of Articles 81 and 82 EC and Articles 53 and 54 of the EEA Agreement by Les Laboratoires Servier (Servier) as well as possible infringement of Article 81 EC by Matrix and four other companies, each of which entered into agreements with Servier relating to the product perindopril. Matrix is cooperating with the EU Commission in connection with the investigation. The EU Commission stated that the initiation of proceedings does not imply that the Commission has conclusive proof of an infringement but merely signifies that the Commission will deal with the case as a matter of priority. No statement of objections has been filed against Matrix in connection with its investigation. On August 5, 2009, Matrix and Generics [U.K.] Ltd. received requests for information from the EU Commission in connection with this matter, and both companies have responded. By letters dated February 17, 2010, the EU Commission served additional requests for information on Matrix and Mylan S.A.S. The companies intend to cooperate in connection with these requests.

In addition, the EU Commission is conducting a pharmaceutical sector inquiry involving approximately 100 companies concerning the introduction of innovative and generic medicines. Mylan S.A.S has responded to the questionnaires received in connection with the sector inquiry and has produced documents and other information in connection with the inquiry.

On October 6, 2009, the Company received notice that the EU Commission was initiating an investigation pursuant to Article 20(4) of Regulation No. 1/2003 to explore possible infringement of Articles 81 and 82 EC by the Company and its affiliates. Mylan S.A.S., acting on behalf of its Mylan affiliates, has produced documents and other information in connection with the inquiry. The Company and Mylan S.A.S. received an additional request for information with the same case reference on December 18, 2009 and have responded to the questionnaire. Mylan is cooperating with the Commission in connection with the investigation. No statement of objections has been filed against Mylan in connection with the investigation.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business, including certain proceedings assumed as a result of the acquisition of the former Merck Generics business. While it is not feasible to predict the ultimate outcome of such other proceedings, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position, results of operations or cash flows.

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ITEM 4. Submission of Matters to a Vote of Security Holders

None.

PART II

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

Prior to December 29, 2008, our common stock was traded on the New York Stock Exchange under the symbol MYL. As of December 29, 2008, 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:

Calendar Year Ended December 31, 2009	High	Low
Three months ended March 31, 2009	$ 13.85	$ 9.65
Three months ended June 30, 2009	14.94	12.50
Three months ended September 30, 2009	16.47	11.66
Three months ended December 31, 2009	19.21	15.42

Calendar Year Ended December 31, 2008	High	Low
Three months ended March 31, 2008	$ 15.49	$ 10.04
Three months ended June 30, 2008	13.54	10.90
Three months ended September 30, 2008	14.45	10.67
Three months ended December 31, 2008	11.55	5.75

As of February 19, 2010, there were approximately 174,250 holders of record of our common stock, including those held in street or nominee name.

On May 12, 2007, in conjunction with the acquisition of the former Merck Generics business, the Company suspended the dividend on its common stock effective upon the completion of the acquisition on October 2, 2007.

The following table shows information about the securities authorized for issuance under Mylan s equity compensation plans as of December 31, 2009:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)

Equity compensation plans approved by security holders	28,644,809	$	15.02	15,677,527
Equity compensation plans not approved by security holders				
Total	28,644,809	$	15.02	15,677,527

In the past three years, we have issued unregistered securities in connection with the following transaction:

On September 15, 2008, Mylan completed the sale of $575.0 million of 3.75% Cash Convertible Notes due 2015 (Cash Convertible Notes). The Cash Convertible Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the Securities Act).

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STOCK PERFORMANCE GRAPH

Set forth below is a performance graph comparing the cumulative total return (assuming reinvestment of dividends) for the three fiscal years ended March 31, 2007, the nine-month period ended December 31, 2007 and the calendar years ended December 31, 2008 and December 31, 2009 of $100 invested on March 31, 2004 in Mylan s Common Stock, the Standard & Poor s 500 Index and the Dow Jones U.S. Pharmaceuticals Index.

	3/04	3/05	3/06	3/07	12/07	12/08	12/09
Mylan Inc.	100.00	78.47	104.85	95.84	63.95	44.98	83.83
S&P 500	100.00	106.69	119.20	133.31	139.74	88.04	111.33
Dow Jones U.S. Pharmaceuticals	100.00	93.33	95.17	105.82	110.24	90.24	107.46

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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 elsewhere 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 (USD). The functional currency of non-U.S. subsidiaries is generally the local currency in the country in which each subsidiary operates.

	Calendar Year Ended[1] December 31, 2009	Calendar Year Ended[2][6] December 31, 2008	Nine Months Ended[3][6] December 31, 2007	Fiscal Year Ended March 31, 2007[4][6]	Fiscal Year Ended March 31, 2006[5][6]
(In thousands, except per share amounts)					
Statements of Operations:					
Total revenues	$ 5,092,785	$ 5,137,585	$ 2,178,761	$ 1,611,819	$ 1,257,164
Cost of sales	3,018,313	3,067,364	1,304,313	768,151	629,548
Gross profit	2,074,472	2,070,221	874,448	843,668	627,616
Operating expenses:					
Research and development	275,258	317,217	146,063	103,692	102,431
Acquired in-process research and development			1,269,036	147,000	
Goodwill impairment		385,000			
Selling, general and administrative	1,050,145	1,053,485	449,598	215,538	225,380
Litigation settlements, net	225,717	16,634	(1,984)	(50,116)	12,417
Earnings (loss) from operations	523,352	297,885	(988,265)	427,554	287,388
Interest expense	318,496	380,779	196,335	53,737	31,285
Other income, net	22,119	11,337	86,611	50,234	18,502
Earnings (loss) before income taxes and noncontrolling interest	226,975	(71,557)	(1,097,989)	424,051	274,605
Income tax (benefit) provision	(20,773)	128,550	53,413	207,449	90,063
Net (earnings) loss attributable to the noncontrolling interest	(15,177)	4,031	3,112	(211)	
Net earnings (loss) attributable to Mylan Inc.	232,571	(196,076)	(1,148,290)	216,391	184,542

before preferred dividends					
Preferred dividends	139,035	139,035	15,999		
Net earnings (loss) attributable to Mylan Inc. common shareholders	$ 93,536	$ (335,111)	$ (1,164,289)	$ 216,391	$ 184,542
Selected Balance Sheet data:					
Total assets	$ 10,801,734	$ 10,409,859	$ 11,353,176	$ 4,253,867	$ 1,870,526
Working capital	1,567,239	1,630,023	1,056,950	1,711,509	926,650
Short-term borrowings	184,352	151,109	144,355	108,259	
Long-term debt, including current portion of long-term debt	4,991,335	5,082,318	5,001,878	1,649,221	687,938
Total equity	3,145,198	2,786,841	3,506,820	1,771,725	787,651
Earnings (loss) per common share attributable to Mylan Inc. common shareholders:					
Basic	$ 0.31	$ (1.10)	$ (4.53)	$ 1.01	$ 0.80
Diluted	$ 0.30	$ (1.10)	$ (4.53)	$ 0.99	$ 0.79
Cash dividends declared and paid	$	$	$ 0.06	$ 0.24	$ 0.24
Weighted average common shares outstanding:					
Basic	305,162	304,360	257,150	215,096	229,389
Diluted	306,913	304,360	257,150	219,120	234,209

(1) Calendar year 2009 cost of sales includes approximately $282.5 million related to the amortization of purchased intangibles and the amortization of the inventory step-up primarily associated with the former Merck Generics business and Matrix acquisitions.

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(2) Calendar year 2008 cost of sales includes approximately $415.6 million related to the amortization of purchased intangibles and the amortization of the inventory step-up primarily associated with the former Merck Generics business and Matrix acquisitions. Calendar year 2008 also includes a goodwill impairment loss of $385.0 million and impairment charges on certain other assets of $72.5 million.

(3) The nine months ended December 31, 2007 includes the results of the former Merck Generics business acquisition from October 2, 2007. In addition to the write-off of acquired in-process research and development of $1.27 billion, cost of sales includes approximately $148.9 million related to the amortization of purchased intangibles and the amortization of the inventory step-up primarily associated with the former Merck Generics business and Matrix acquisitions.

(4) Fiscal year 2007 includes the results of the Matrix acquisition from January 8, 2007. In addition to the write-off of acquired in-process research and development of $147.0 million, cost of sales includes approximately $17.6 million primarily related to the amortization of intangibles and the inventory step-up primarily associated with the acquisition.

(5) Fiscal year 2006 does not include stock-based compensation expense, because the adoption of the guidance issued by the Financial Accounting Standards Board (FASB) that requires the recognition in the financial statements of such expense did not occur until April 1, 2006, and the Company elected the prospective method.

(6) Calendar year 2008, the nine months ended December 31, 2007, and fiscal years 2007 and 2006 have been revised in accordance with the updated accounting guidance regarding noncontrolling interests and accounting related to the Company s outstanding Convertible Notes which the Company adopted on January 1, 2009. See Note 2 to Consolidated Financial Statements.

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

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

This Form 10-K may contain forward-looking statements . These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about our market opportunities, strategies, competition and expected activities and expenditures, and at times may be identified by the use of words such as may , could , should , would , project , be anticipate , expect , plan , estimate , forecast , potential , intend , continue and variations of these words or c words. Forward-looking statements inherently involve risks and uncertainties. Accordingly, actual results may differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the risks described above under Risk Factors in Part I, Item 1A. We undertake no obligation to update any forward-looking statements for revisions or changes after the date of this Form 10-K.

Executive Overview

Mylan is the world s third largest producer of generic and specialty pharmaceuticals, offering one of the industry s broadest and highest quality product portfolios, a robust pipeline and a global commercial footprint that spans more than 140 countries and territories. Employing over 15,500 people, Mylan has attained leading positions in key

international markets through its wide array of dosage forms and delivery systems, significant manufacturing capacity, global scale and commitment to customer service. Through its Matrix Laboratories Limited (Matrix) subsidiary, Mylan controls one of the world s largest active pharmaceutical ingredient (API) manufacturers with respect to the number of drug master files (DMFs) filed with regulatory agencies. This relationship makes Mylan one of only two global generics companies with a comprehensive, vertically integrated supply chain. We hold a leading generics sales position in four of the world s largest pharmaceutical markets, those being the United States (U.S.), France, the United Kingdom (U.K.) and Japan, and we also hold leading sales positions in several other key generics markets, including Australia, Belgium, Italy, Portugal and Spain.

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Mylan previously had three reportable segments, Generics , Specialty and Matrix. The Matrix Segment had consisted of Matrix, which was previously a publicly traded company in India, in which Mylan held a 71.2% ownership stake. Following the acquisition of approximately 25% of the remaining interest in Matrix and its related delisting from the Indian stock exchanges, Mylan now has two reportable segments, Generics and Specialty. Mylan changed its segments to align with how the business is being managed after those changes. The former Matrix Segment is included within the Generics Segment. Information for earlier periods has been recast.

Generics primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule or transdermal patch form, as well as API. Specialty engages mainly in the manufacture and sale of branded specialty nebulized and injectable products. We also report in Corporate/Other certain research and development expenses, general and administrative expenses; litigation settlements; amortization of intangible assets and certain purchase-accounting items (such as the inventory step-up); impairment charges; and other items not directly attributable to the segments.

Change in Fiscal Year

Effective October 2, 2007, we changed our fiscal year end from March 31st to December 31st. We have defined various periods that are covered in the discussion below as follows:

calendar year 2009 January 1, 2009 through December 31, 2009;

calendar year 2008 January 1, 2008 through December 31, 2008;

calendar year 2007 January 1, 2007 through December 31, 2007;

transition period April 1, 2007 through December 31, 2007; and

comparable nine-month period April 1, 2006 through December 31, 2006.

The above periods include Matrix from January 8, 2007 and the former Merck Generics business from October 2, 2007. As a result of the change in year end, we believe that a comparison between calendar year 2008 and calendar year 2007 and a comparison between the transition period and the comparable nine-month period enhances a reader s understanding of our results of operations and, as such, these are the comparisons which are presented below in the section titled Results of Operations . The financial and operational trends highlighted in the comparisons presented below are consistent with those that would result from a comparison of calendar year 2008 to the transition period.

Acquisition of the Remaining Interest in Matrix Laboratories Limited

On March 26, 2009, we announced plans to buy the remaining public interest in Matrix from its minority shareholders pursuant to a voluntary delisting offer. At the time, we owned approximately 71.2% of Matrix through a wholly-owned subsidiary, and controlled more than 76% of its voting rights. On June 1, 2009, Mylan announced that it had successfully completed the delisting offer and accepted the discovered price of 211 Rupees per share, which was established by the reverse book building process prescribed by Indian regulations. During the calendar year ended December 31, 2009, we completed the purchase of an additional portion of the remaining interest from minority shareholders of Matrix, for cash of approximately $182.2 million, bringing both our total ownership and control to over 96%. Matrix s stock was delisted from the Indian stock exchanges effective August 21, 2009.

Bystolic[tm]

In January 2006, we announced an agreement with Forest Laboratories Holdings, Ltd. (Forest), a wholly-owned subsidiary of Forest Laboratories, Inc., for the commercialization, development and distribution of Bystolic in the United States and Canada (the 2006 Agreement). Under the terms of that agreement, Mylan received a $75.0 million up-front payment and $25.0 million upon approval of the product. Such amounts were being deferred until the commercial launch of the product and were to be amortized over the remaining term of the license agreement. Mylan also had the potential to earn future milestones and royalties on Bystolic sales and an option to co-promote the product, while Forest assumed all future development and selling and marketing expenses.

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In February 2008, Mylan executed an agreement with Forest whereby Mylan sold to Forest its rights to Bystolic (the Amended Agreement). Under the terms of the Amended Agreement, Mylan received a cash payment of $370.0 million, which was deferred along with the $100.0 million received under the 2006 Agreement, and retained its contractual royalties for three years, through 2010. Mylan s obligations under the 2006 Agreement to supply Bystolic to Forest were unchanged by the Amended Agreement. Mylan believed that these supply obligations represented significant continuing involvement as Mylan remained contractually obligated to manufacture the product for Forest while the product was being commercialized. As a result of this continuing involvement, Mylan had been amortizing the $470.0 million of deferred revenue ratably through 2020 pending the transfer of manufacturing responsibility that was anticipated to occur in the second half of 2008.

In September 2008, Mylan completed the transfer of all manufacturing responsibilities for the product to Forest, and Mylan s supply obligations have therefore been eliminated. We believe that we no longer have significant continuing involvement and that the earnings process has been completed. As such, the deferred revenue of $468.1 million was recognized and included in other revenues in our Consolidated Statements of Operations for calendar year 2008.

Future royalties are considered to be contingent consideration and are recognized in other revenue as earned upon sales of the product by Forest. Such royalties are recorded at the net royalty rates specified in the Amended Agreement.

Goodwill Impairment

On February 27, 2008 we announced that we were reviewing strategic alternatives for our specialty business, Dey, including the potential sale of the business. This decision was based upon several factors, including a strategic review of the business, the expected performance of the Perforomist® product, where anticipated growth was determined to be slower than expected and the timeframe to reach peak sales was determined to be longer than was originally anticipated.

As a result of our ongoing review of strategic alternatives, we determined that it was more likely than not that the business would be sold or otherwise disposed of significantly before the end of its previously estimated useful life. Accordingly, a recoverability test of Dey s long-lived assets was performed during the three months ended March 31, 2008. We included both cash flow projections and estimated proceeds from the eventual disposition of the long-lived assets. The estimated undiscounted future cash flows exceeded the book values of the long-lived assets and, as a result, no impairment charge was recorded.

Upon the closing of the former Merck Generics business acquisition, Dey was defined as the Specialty Segment. Dey is also considered a reporting unit. Upon closing of the transaction, we allocated $711.2 million of goodwill to Dey.

We test goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. As we had determined that it was more likely than not that the business would be sold or otherwise disposed of significantly before the end of its previously estimated useful life, we were required, during the three months ended March 31, 2008, to assess whether any portion of its recorded goodwill balance was impaired.

The first step of the impairment analysis consisted of a comparison of the fair value of the reporting unit with its carrying amount, including the goodwill. We performed extensive valuation analyses, utilizing both income and market-based approaches, in our goodwill assessment process. The following describes the valuation methodologies used to derive the estimated fair value of the reporting unit.

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

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Market-Based Approach: To corroborate the results of the income approach described above, we estimated the fair value of our reporting unit using several market-based approaches, including the guideline company method which focused on comparing our risk profile and growth prospects to a select group of publicly traded companies with reasonably similar guidelines.

Based on the step one analysis that was performed for Dey, we determined that the carrying amount of the net assets of the reporting unit was in excess of its estimated fair value. As such, we were required to perform the step two analysis for Dey, in order to determine the amount of any goodwill impairment. The step two analysis consisted of comparing the implied fair value of the goodwill with the carrying amount of the goodwill, with an impairment charge resulting from any excess of the carrying value of the goodwill over the implied fair value of the goodwill based on a hypothetical allocation of the estimated fair value to the net assets. Based on the second step analysis, we concluded that $385.0 million of the goodwill recorded at Dey was impaired. As a result, we recorded a goodwill impairment charge of $385.0 million during the three months ended March 31, 2008, which represented our best estimate as of March 31, 2008. The allocation discussed above was performed only for purposes of assessing goodwill for impairment; accordingly, we have not adjusted the net book value of the assets and liabilities on our Consolidated Balance Sheet, other than goodwill, as a result of this process.

The determination of the fair value of the reporting unit required us to make significant estimates and assumptions that affect the reporting unit s expected future cash flows. These estimates and assumptions primarily include, but are not limited to, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. In addition, changes in underlying assumptions would have a significant impact on either the fair value of the reporting unit or the goodwill impairment charge.

The hypothetical allocation of the fair value of the reporting unit to individual assets and liabilities within the reporting unit also requires us to make significant estimates and assumptions. The hypothetical allocation requires several analyses to determine the estimate of the fair value of assets and liabilities of the reporting unit.

In September 2008, following the completion of the comprehensive review of strategic alternatives for Dey, we announced our decision to retain the Dey business. This decision included a plan to realign the business, which has resulted in the incurrence of severance and other exit costs. In addition, the comprehensive review resulted in an intangible asset impairment charge related to certain non-core, insignificant, third-party products.

Product Opportunities

On November 10, 2009, Mylan announced that Matrix received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for lansoprazole delayed-release (DR) capsules, 15 mg and 30 mg. Lansoprazole DR capsules are the generic version of Tap Pharmaceuticals proton pump inhibitor Prevacid® DR Capsules. The brand product had U.S. sales of approximately $3.0 billion for the twelve months ended June 30, 2009, according to IMS Health. Mylan began shipment of its product immediately upon approval, and began selling it under the Mylan Pharmaceuticals Inc. (MPI) brand.

On January 30, 2009, we announced that MPI received final approval from the FDA for our ANDA for divalproex sodium extended-release (divalproex ER) tablets, 250 mg and 500 mg. Divalproex ER tablets are the generic version of Abbott Laboratories Depakote® ER and had U.S. sales of approximately $901.0 million for the twelve months ended September 30, 2008, with $789.0 million for the 500 mg strength and $112.0 million for the 250 mg strength, according to IMS. Mylan began shipment of its 250 mg product immediately upon approval. Mylan was awarded 180 days of marketing exclusivity for the 500 mg strength, which it began to ship on February 2, 2009. Mylan began shipment of its 250 mg product immediately upon approval.

On November 4, 2008, we announced that MPI received final approval from the FDA for our ANDA for levetiracetam tablets, 250 mg, 500 mg and 750 mg. Levetiracetam tablets are the generic version of UCB Pharma s Keppra®. Levetiracetam tablets had U.S. sales of approximately $1.0 billion for the twelve months ended September 30, 2008 for these three strengths, according to IMS. Pursuant to an agreement with UCB Societe Anonyme and UCB Pharma Inc. to settle pending litigation relating to levetiracetam tablets, Mylan began shipment of its product immediately upon approval. Additional generic competition entered the market in mid-January 2009.

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Financial Summary

For the year ended December 31, 2009, Mylan reported total revenues of $5.09 billion compared to $5.14 billion for 2008. Included in total revenues for the year ended December 31, 2008 was $468.1 million of previously deferred revenue related to our sale of the product rights of Bystolic™. Excluding this, total revenues increased $423.3 million over the prior year. Consolidated gross profit for both periods remained consistent at $2.07 billion. Excluding Bystolic from the prior year, gross profit for 2009 increased by 29.5%. For the current year, operating income of $523.4 million was realized compared to $297.9 million in the prior year. Excluding Bystolic from the prior year, as well as an impairment charge of $385.0 million as further discussed below, operating income for 2008 was $214.8 million.

The net earnings attributable to Mylan Inc. common shareholders for the current year were $93.5 million compared to a loss of $335.1 million in the comparable prior year period. This translates into earnings per diluted share attributable to Mylan Inc. of $0.30 for calendar year 2009, compared to a loss per diluted share of $1.10 in the calendar year 2008.

Included in the results for calendar year 2009 and 2008 are the following items of note:

Calendar year 2009:

Charges consisting primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of the former Merck Generics business of $282.5 million;

Other revenue of approximately $28.5 million resulting from the cancellation of product development agreements for which the revenue had been previously deferred;

Net litigation charges of $225.7 million consisting primarily of a charge of $160 million related to a settlement in principle to resolve certain claims relating to the Company s outstanding pricing litigation and to reserve for the remaining pricing lawsuits to which the Company is a party, and a charge of $121.0 million related to the settlement of an investigation by the U.S. Department of Justice, concerning calculations of Medicaid drug rebates, partially offset by certain litigation related recoveries;

Interest of $42.9 million relating to the accretion of the discounts on our convertible debt instruments;

An upfront payment of $18.0 million made with respect to the execution of a co-development agreement;

Rebranding costs associated with a migration to the Mylan brand for the former Merck Generics business totaling $21.4 million;

Additional costs, primarily restructuring, related to the integration of recently acquired entities, and other costs, totaling $60.7 million;

A tax effect of $207.5 million related to the above items and other taxes; and

An income tax benefit of approximately $65.0 million related to losses recognized as a result of reorganizations among certain of our foreign subsidiaries.

Calendar year 2008:

Charges consisting primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of the former Merck Generics business of $415.6 million;

The recognition of $468.1 million of deferred revenue related to Mylan s sale of the product rights of Bystolic;

An impairment loss on the goodwill of the Dey business of $385.0 million;

Intangible asset impairment charges of $72.5 million on certain non-core, insignificant, third-party products;

Net litigation charges of $16.6 million related to the settlement of litigation, the majority of which relates to the awarding of attorney s fees in a patent infringement case in which Mylan was the defendant;

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Interest of $29.5 million relating to the accretion of the discounts on our convertible debt instruments;

Rebranding costs associated with a migration to the Mylan brand for the former Merck Generics business totaling $42.9 million;

Consulting and information technology (IT) costs directly associated with the integration of newly acquired businesses totaling approximately $38.7 million;

Additional costs, other than consulting and IT, primarily restructuring, related to the integration of recently acquired entities, and other costs, totaling $77.2 million; and

A tax effect of $30.6 million related to the above items and other taxes.

A more detailed discussion of our financial results can be found below in the section titled Results of Operations .

Results of Operations

	Calendar Year December 31,			Nine Months December 31,	
	2009	2008	2007	2007	2006
			(Unaudited)		(Unaudited)
	(In thousands, except per share amounts)				
Revenues:					
Net revenues	$ 5,015,394	$ 4,631,237	$ 2,646,643	$ 2,162,943	$ 1,103,247
Other revenues	77,391	506,348	19,380	15,818	21,310
Total revenues	5,092,785	5,137,585	2,666,023	2,178,761	1,124,557
Cost of sales	3,018,313	3,067,364	1,556,728	1,304,313	515,736
Gross profit	2,074,472	2,070,221	1,109,295	874,448	608,821
Operating expenses:					
Research and development	275,258	317,217	182,911	146,063	66,844
Acquired in-process research and development			1,416,036	1,269,036	
Goodwill impairment		385,000			
Selling, general and administrative	1,050,145	1,053,485	512,387	449,598	152,784
Litigation settlements, net	225,717	16,634	(5,981)	(1,984)	(46,154)
Total operating expenses	1,551,120	1,772,336	2,105,353	1,862,713	173,474
Earnings (loss) from operations	523,352	297,885	(996,058)	(988,265)	435,347
Interest expense	318,496	380,779	218,780	196,335	31,292
Other income, net	22,119	11,337	97,060	86,611	39,785
	226,975	(71,557)	(1,117,778)	(1,097,989)	443,840

Earnings (loss) before income taxes and noncontrolling interest					
Income tax (benefit) provision	(20,773)	128,550	105,595	53,413	155,267
Net earnings (loss)	247,748	(200,107)	(1,223,373)	(1,151,402)	288,573
Net (earnings) loss attributable to the noncontrolling interest	(15,177)	4,031	2,901	3,112	
Net earnings (loss) attributable to Mylan Inc. before preferred dividends	232,571	(196,076)	(1,220,472)	(1,148,290)	288,573
Preferred dividends	139,035	139,035	15,999	15,999	
Net earnings (loss) attributable to Mylan Inc. common shareholders	$ 93,536	$ (335,111)	$ (1,236,471)	$ (1,164,289)	$ 288,573
Earnings (loss) per common share attributable to Mylan Inc.:					
Basic	$ 0.31	$ (1.10)	$ (4.95)	$ (4.53)	$ 1.37
Diluted	$ 0.30	$ (1.10)	$ (4.95)	$ (4.53)	$ 1.34
Weighted average common shares outstanding:					
Basic	305,162	304,360	249,652	257,150	211,075
Diluted	306,913	304,360	249,652	257,150	215,275

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Calendar Year 2009 Compared to Calendar Year 2008

For calendar year 2009, Mylan reported total revenues of $5.09 billion compared to $5.14 billion in the same prior year period. Total revenue includes both net sales to third parties and other revenue. Net sales for 2009 were $5.02 billion compared to $4.63 billion for 2008, representing an increase of $384.2 million, or 8%. Net sales were unfavorably impacted by the effect of foreign currency translation, primarily reflecting a stronger U.S. dollar in comparison to the functional currencies of Mylan s other subsidiaries, primarily those in Europe, Australia and India. Translating current year revenues at prior year exchange rates would have resulted in year-over-year growth in net sales excluding foreign currency of $558.9 million, or approximately 12%.

Other revenues for 2009 were $77.4 million compared to $506.3 million in 2008, a decrease of $429.0 million. Included in other revenue for the prior year is the recognition of $468.1 million of previously deferred revenue related to the sale of our rights of Bystolic. Excluding this item, other revenues increased in the current year mainly due to incremental revenue resulting from the cancellation of product development agreements for which the revenue had been previously deferred. Prior to the termination of these agreements, Mylan had been amortizing the previously received non-refundable payments over a period of several years.

In arriving at net revenues, gross revenues are reduced by provisions for estimates, including discounts, customer performance, indirect rebates and promotions, price adjustments, returns and chargebacks. See the section titled *Application of Critical Accounting Policies* in this Item 7, for a thorough discussion of our methodology with respect to such provisions. For calendar year ended December 31, 2009, the most significant amounts charged against gross revenues were for chargebacks in the amount of $1.89 billion and promotions and indirect rebates in the amount of $1.08 billion.

Gross profit for calendar year 2009 was $2.07 billion and gross margins were 40.7%. For calendar year 2008, gross profit was $2.07 billion and gross margins were 40.3%. Gross profit was impacted by certain purchase accounting related items recorded during calendar year 2009 of approximately $282.5 million, which consisted primarily of incremental amortization related to the purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of the former Merck Generics business. Excluding these items, gross margins would have been approximately 46.3%. Prior year gross profit is also impacted by similar purchase accounting related items in the amount of $481.4 million, including certain intangible assets impairment charges. Excluding such items, as well as the Bystolic revenue, gross margins in the prior year would have been approximately 44.6%.

The increase in gross margins, excluding the items noted above, can generally be attributed to the impact of the timing of significant product launches. Products generally contribute most significantly to gross margin at the time of their launch and even more so in periods of market exclusivity or limited generic competition. As discussed previously, during calendar year 2009, we launched divalproex ER and lansoprazole DR.

Generics Segment

For calendar year 2009, the Generics Segment reported total revenues of $4.70 billion compared to $4.29 billion in calendar year 2008, an increase of $413.0 million, or 9.6%. However, excluding the effect of foreign currency, calculated as described previously, the increase was approximately 13%. Generics Segment total revenues are derived from sales primarily in or from the U.S. and Canada (collectively North America), Europe, Middle East and Africa (collectively, EMEA) and India, Australia, Japan, and New Zealand (collectively, Asia Pacific).

Total revenues from North America were $2.18 billion for calendar year 2009 compared to $1.87 billion for calendar year 2008, representing an increase of $307.9 million, or 16.4%. The increase is due primarily to new product revenue in the U.S. and Canada. New products contributed net revenues of approximately $322.5 million, the majority of

which were divalproex ER and lansoprazole DR. Year over year decreases from our existing products were driven by unfavorable pricing, largely offset by increased volume. Loss of exclusivity and increased competition on certain products drove price declines, while volumes were favorably impacted by Mylan s ability to remain a source of stable supply as certain competitors experienced regulatory and supply issues.

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Fentanyl, our AB-rated generic alternative to Duragesic®, continued to contribute to both revenue and gross profit despite the entrance into the market of additional generic competition. Sales of fentanyl have remained relatively strong primarily due to Mylan s ability to continue to be a stable and reliable source of supply to the market. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. Competition on fentanyl in the future could continue to have an unfavorable impact on pricing and market share.

Included in total revenues from North America are other revenues of $54.6 million in the current year versus $26.4 million in the prior year. This increase in other revenues is primarily the result of incremental revenue resulting from the cancellation of certain product development agreements of $28.5 million, as discussed previously.

Total revenues from EMEA were $1.66 billion for calendar year 2009 compared to $1.64 billion for calendar year 2008, an increase of $18.5 million, or 1.1%. However, excluding the effect of foreign currency, calculated as described previously, the increase was approximately $136.0 million, or 8%. The increase was driven by new product launches, favorable market dynamics in certain countries, and a full year of revenue contribution from the Central and Eastern European businesses acquired in June 2008.

The launch of new products and increased product volumes resulted in overall higher revenues in Spain, Italy and France, the latter of which also realized sales growth across all sectors, mainly as a result of a gain in market share. In Italy, the increase in revenues was also driven by regulatory changes that have had a significant favorable impact on pricing. In the U.K., prior year revenues were negatively impacted by excess supply in the market at that time. The increase in the current year is the result of such excess supply issues having since been resolved.

Revenues in Germany were negatively affected by recently implemented tender systems. A number of markets in which we operate have implemented or may implement such tender systems for generic pharmaceuticals in an effort to lower prices. These measures have a negative impact on sales and gross profit in the affected markets. In Germany, current year revenues were negatively impacted by the price reductions as a result of these tenders, as well as general pricing pressure on its non-tender business and the loss of exclusivity on certain Statutory Health Insurance contracts.

In Asia Pacific, total revenues were $1.0 billion for calendar year 2009 compared to $911.1 million for calendar year 2008, an increase of $90.3 million, or 9.9%. However, excluding the effect of foreign currency, calculated as described above, the increase was approximately $151.0 million, or 17%. Sales in Asia Pacific are derived from the sale of generic pharmaceuticals in Australia, India, Japan and New Zealand, as well as API by our Matrix subsidiary in India. Driving the year over year revenue increase was the sale of generics and API and increased sales in Japan.

Certain markets in which we do business have recently undergone government-imposed price reductions, thereby increasing pricing pressures on pharmaceutical products. This is true in Australia as well as several European countries. Such measures, along with the tender systems discussed above, 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 unfavorability by potentially increasing generic substitution. In Australia, the impact of the government-imposed pricing reform was the primary reason for the overall decrease in revenues. Partially offsetting this decrease were favorable volumes when compared to 2008.

In India, third party sales of both finished dosage form (FDF) generics and API drove year over year growth. The increase in FDF is primarily due to continued growth in anti-retroviral (ARV) products, including the awarding in the current year of several key contracts and tenders, while third party sales of API were driven by significant product launches in the U.S. and Europe. Additionally, during 2009, the Company acquired the remaining 50% of a joint venture that had been accounted for using the equity method of accounting. Subsequent to this acquisition, the revenues generated by this subsidiary are included in Matrix s total revenues. Matrix also sells API to other Mylan

subsidiaries in conjunction with our vertical integration strategy.

In Japan, sales increased over the prior year due to Mylan s growth in the Japanese market and the continued impact of certain pro-generic measures implemented by the Japanese government.

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In addition to net sales, included in total revenues in Asia Pacific are other revenues of $56.4 million for 2009, compared to $46.0 million in 2008. Other revenues are realized primarily through intercompany product development agreements.

Specialty Segment

For calendar year 2009 the Specialty Segment reported total revenues of $455.7 million, of which $415.0 million represented sales to third-parties. For calendar year 2008, the Specialty Segment reported total revenues of $417.2 million, of which $386.0 million represented sales to third-parties. The most significant contributor to the Specialty Segment revenues is EpiPen® Auto-injector, which is used in the treatment of severe allergic reactions. The EpiPen Auto-injector is the number one prescribed treatment for severe allergic reactions with a U.S. market share of 96%.

In addition to the continued strong sales of the EpiPen Auto-injector, the increase in third-party revenues was driven by increased sales of Perforomist® Solution, Dey s maintenance therapy for patients with moderate to severe chronic obstructive pulmonary disease. Increased sales of the EpiPen Auto-injector and Perforomist Solution in the current year were partially offset by lower revenue from DuoNeb® for which patent protection was lost in late 2007. The additional competition which followed the loss of patent protection has not only affected Dey s sales of the branded product, but also impacted the profit share received from sales of the licensed generic.

Operating Expenses

Research and development (R&D) expense for calendar year 2009 was $275.3 million compared to $317.2 million for calendar year 2008, a decrease of $42.0 million or 13.2%. The decrease in R&D was driven by decreases in both Generics and Specialty, and the favorable impact of foreign exchange, partially offset by an increase in Corporate/Other. The decreases in Generics and Specialty are reflective of certain restructuring activities with respect to the previously announced rationalization and optimization of the global manufacturing and research and development platforms. The overall decreases in Generics and Specialty were partially offset by an increase in Corporate/Other driven by an up-front payment of $18.0 million made with respect to our execution of a co-development agreement.

Selling, general and administrative (SG&A) expense for calendar year 2009 was flat year over year at $1.05 billion, with decreases in Generics and Specialty offset by an increase in Corporate/Other. The decrease in Generics was driven primarily by the effect of foreign exchange, partially offset by costs related to the restructurings referred to above. The cost savings as a result of these restructurings began to materialize in 2009, but is expected to have a more favorable impact on future periods. However, the benefit from the restructuring programs in Specialty was a driver, along with a decrease in professional fees, of lower SG&A in the current year in that segment

These decreases in SG&A explained above were offset by an increase in Corporate/Other due primarily to an increase in legal and professional fees, as well as higher payroll and payroll-related costs.

Litigation Settlements, net

During calendar year 2009, we recorded net unfavorable litigation charges of $225.7 million. This amount consists primarily of a charge of $160 million related to a settlement in principle to resolve certain claims relating to the Company s outstanding pricing litigation, and to reserve for the remaining pricing lawsuits to which the Company is a party, and a charge of $121 million related to the settlement of an investigation by the U.S. Department of Justice, concerning calculations of Medicaid drug rebates offset by certain litigation-related recoveries.

Interest Expense

Interest expense for calendar year 2009 totaled $318.5 million compared to $380.8 million for calendar year 2008. In March 2009, we pre-paid all of our required 2010 principal payments, and in December 2009 we pre-paid all of our required 2011 principal payments on our term debt, which, along with lower overall interest rates, drove

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the decrease in interest expense. Included in interest expense for 2009 and 2008 are $42.9 million and $29.5 million of accretion of the discounts on our convertible debt instruments.

Other Income, net

Other income, net, was $22.1 million for calendar year 2009, compared to $11.3 million in calendar year 2008. Other income in 2009 included a favorable adjustment of $13.9 million to the restructuring reserve as a result of a reduction in the estimated remaining spending on accrued projects, a $10.4 million net gain realized on the termination of certain joint ventures by our Matrix subsidiary, and interest income of $6.7 million, partially offset by a $11.7 million loss on the sale, by Matrix, of a majority-owned subsidiary. In the prior year, other income was primarily comprised of interest and dividend income.

Income Tax Expense

For calendar year 2009, income taxes were a benefit of $20.8 million as compared to a $128.6 million expense for calendar year 2008. The current year included a $65.0 million tax benefit related to losses recognized as a result of reorganizations among certain of our foreign subsidiaries. In calendar year 2008, a pre-tax operating loss was offset by the non-deductible goodwill impairment charge related to Dey. The effective tax rate in the prior year was largely influenced by the gain on the sale of Bystolic as well. In addition to these items, the change in the provision year over year was driven primarily by the deductibility of certain foreign attributes, changes in unrecognized losses of certain foreign subsidiaries, different levels of income, and changes to our tax reserves as required by the FASB s Accounting Standards Codification (Codification) topic regarding income taxes.

Calendar Year 2008 Compared to Calendar Year 2007

Total Revenues and Gross Profit

For calendar year 2008, Mylan reported total revenues of $5.14 billion compared to $2.67 billion in the same prior year period. This represents an increase of $2.47 billion. In calendar year 2008, the former Merck Generics business contributed third-party revenues of $2.57 billion of which $2.19 billion are included in the Generics Segment and $386.0 million are included in the Specialty Segment. In calendar year 2007, for the three months following the date of acquisition, the former Merck Generics business contributed third-party revenues of $700.6 million of which $598.5 million are included in the Generics Segment and $102.1 million are included in the Specialty Segment. Also included in total revenues for the current year is $468.1 million of previously deferred revenue recognized related to the sale of our rights of Bystolic. Excluding revenue contributed by the former Merck Generics business for both years, and the Bystolic revenue in the current year, total sales for calendar year 2008 were $2.10 billion compared to $1.97 billion. This represents an increase of approximately 6.7% or $131.0 million over the comparable twelve-month period.

In arriving at net revenues, gross revenues are reduced by provisions for estimates, including discounts, customer performance, indirect rebates and promotions, price adjustments, returns and chargebacks. See the section titled *Application of Critical Accounting Policies* in this Item 7, for a thorough discussion of our methodology with respect to such provisions. For calendar year ended December 31, 2008, the most significant amounts charged against gross revenues were for chargebacks in the amount of $1.46 billion and promotions and indirect rebates in the amount of $753.7 million.

Gross profit for calendar year 2008 was $2.07 billion and gross margins were 40.3%. For calendar year 2007, gross profit was $1.11 billion and gross margins were 41.6%. Gross profit was impacted by certain purchase accounting related items recorded during calendar year 2008 of approximately $415.6 million, which consisted primarily of

incremental amortization related to the purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of the former Merck Generics business. In addition, gross profit is impacted by certain non-cash impairment charges of $65.7 million recorded during the calendar year ended December 31, 2008. Excluding these items, as well as the Bystolic revenue, gross margins would have been approximately 44.6%. Prior year gross profit is also impacted by similar purchase accounting related items recorded primarily with respect to the acquisition of the former Merck Generics business and the acquisition of Matrix in the

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amount of $170.8 million. Excluding such items, gross margins in the prior year would have been approximately 48.0%.

The decrease in gross margins, excluding the items noted above, can generally be attributed to the fact that, on average, the newly acquired former Merck Generics business, particularly in countries outside of the United States, contributes margins that are lower than those realized by Mylan s U.S. subsidiaries. The impact of these lower margins was realized for a full twelve months in calendar year 2008 compared to only three months in calendar year 2007. Additionally, gross margin is impacted by the timing of significant product launches. Products generally contribute most significantly to gross margin at the time of their launch and even more so in periods of market exclusivity or limited generic competition. For a period of time during calendar year 2007, Mylan had exclusivity on both amlodipine and oxybutynin. In the calendar year 2008, Mylan had exclusivity on levetiracetam upon its launch of the product on November 4, 2008.

Generics Segment

For calendar year 2008, the Generics Segment reported total revenues of $4.29 billion compared to $2.56 billion in calendar year 2007. Total revenues from North America were $1.87 billion for calendar year 2008 compared to $1.68 billion for calendar year 2007, representing an increase of $195.3 million. Excluding revenue contributed from the acquisition of the former Merck Generics business from both periods, total North America revenues increased by $99.8 million or 6.2%. This increase is the result of new product revenue and favorable volume, as doses shipped during the twelve months, excluding the impact of the acquisition, increased by 6.6% to 16.7 billion, partially offset by unfavorable pricing.

Fentanyl, Mylan s AB-rated generic alternative to Duragesic®, continued to contribute significantly to the financial results despite the entrance into the market of additional generic competition. As expected, the additional competition had an unfavorable impact on fentanyl pricing, and we expect that additional competition in the future could further impact pricing and market share. However, this was offset by increased volumes of fentanyl which Mylan was able to supply to the market as certain competitors experienced recall and supply issues.

Additional generic competition resulted in unfavorable pricing on several other significant products in our portfolio. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. For one product in particular, amlodipine, Mylan had market exclusivity for a portion of calendar year 2007. As a result, amlodipine accounted for approximately 7% of calendar year 2007 North American revenues (excluding the former Merck Generics business). Additional generic competition was especially heavy on amlodipine and, as a result, calendar year 2008 revenues were insignificant.

In order to offset decreases in sales as a result of additional competition, generic pharmaceutical manufacturers must be able to successfully bring new products to market. Products launched in the U.S. during calendar year 2008 contributed revenues of $264.0 million, with paroxetine extended-release and levetiracetam accounting for the majority.

Total revenues from EMEA were $1.64 billion for calendar year 2008 compared to $493.0 million for calendar year 2007. This increase is the result of a full year of revenues from the former Merck Generics business in 2008.

Total revenues from Asia Pacific were $911.1 million for calendar year 2008 compared to $440.6 million for calendar year 2007. In 2008, $537.4 million of revenues were generated by the former Merck Generics business, compared to $170.9 million in 2007, which is the result of having a full year impact from the former Merck Generics business, compared to only three months post-acquisition in 2007. In 2008, Matrix revenues, included in Asia Pacific, totaled $334.0 million in total revenues, compared to $269.7 million during 2007. Matrix third-party net revenues are from

the sale of both API and FDF ARV products. Matrix launched its FDF business in late calendar year 2007. In addition to its net revenue, Matrix realized other revenue of $44.9 million through intrasegment product development agreements.

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Certain markets in which we do business have recently undergone, some for the first time, or will soon undergo, government-imposed price reductions or similar pricing pressures on pharmaceutical products. This is true in France and Australia, though this issue is not limited to solely these markets. 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 unfavorability by potentially increasing generic substitution.

Specialty Segment

For calendar year 2008, the Specialty Segment reported total revenues of $417.2 million, of which $386.0 million represented sales to third-parties. For calendar year 2007, from the date of acquisition, the Specialty Segment reported total revenues of $105.5 million, of which $102.1 million represented sales to third-parties. The Specialty Segment consists of Dey, an entity acquired as part of the former Merck Generics business that focuses on the development, manufacturing and marketing of specialty pharmaceuticals in the respiratory and severe allergy markets. The most significant contributor to the Specialty Segment revenues is EpiPen Auto-injector, an epinephrine auto-injector, which is used in the treatment of severe allergies. EpiPen Auto-injector is the number one prescribed treatment for severe allergic reactions.

Operating Expenses

R&D expense for calendar year 2008 was $317.2 million compared to $182.9 million for calendar year 2007. Excluding R&D expense incurred by the former Merck Generics business for both years, R&D increased by $22.6 million or 16.3% primarily as a result of increased ANDA and other regulatory submissions, payments incurred with respect to product development agreements, and higher expenses associated with Matrix s launch of its FDF franchise.

During calendar year 2007, we recognized charges of $147.0 million to write-off acquired in-process R&D associated with the Matrix acquisition and $1.27 billion to write-off acquired in-process R&D associated with the acquisition of the former Merck Generics business. These amounts represent the fair value of purchased in-process technology for research projects that, as of the closing dates of the acquisitions, had not reached technological feasibility and had no alternative future use.

SG&A expense for calendar year 2008 was $1.05 billion compared to $512.4 million for the prior year, an increase of $541.1 million. Excluding SG&A expense incurred by the former Merck Generics business for both years, SG&A expense increased by $73.5 million or 20.5%. This increase was primarily realized by Corporate/Other and the Generics Segment. The increase in Corporate/Other SG&A expense is due primarily to an increase in professional and consulting fees as well as higher payroll and payroll related costs. The increase in professional and consulting fees is associated primarily with the ongoing integration of the former Merck Generics business. The increase in payroll and related costs is principally attributable to the build-up of additional corporate infrastructure as a direct result of the acquisition.

The increase in SG&A in the Generics Segment is primarily due to costs incurred with respect to a restructuring of Matrix s European distribution business, including the closure of several dormant entities.

Litigation Settlements, net

During calendar year 2008, we recorded net charges of $16.6 million related to the settlement of outstanding litigation. Of this amount, the majority relates to the awarding of attorneys fees in a patent infringement case in which

Mylan was the defendant.

Interest Expense

Interest expense for calendar year 2008 totaled $380.8 million compared to $218.8 million for calendar year 2007. The increase is due to the additional debt incurred to finance the acquisition of the former Merck Generics business during the fourth quarter of calendar year 2007.

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Other Income, net

Other income, net, was $11.3 million for calendar year 2008, compared to $97.1 million in calendar year 2007. Calendar year 2007 included a $85.0 million non-cash mark-to-market unrealized gain on a deal-contingent foreign currency option contract that was entered into for the then pending acquisition of the former Merck Generics business, and a loss of $57.2 million on the early repayment of debt related to a tender offer made to holders of our Senior Notes and financing fees related to an interim term loan.

Excluding these items, other income decreased in calendar year 2008 primarily due to lower interest and dividend income as a result of lower cash balances and available-for-sale securities.

Income Tax Expense

For calendar year 2008, income tax expense was $128.6 million as compared to $105.6 million for calendar year 2007. The effective tax rate in 2008 was largely influenced by the gain on the sale of Bystolic product rights and the non-deductible non-cash goodwill impairment charge related to Dey. The effective tax rate in the comparable twelve-month period was impacted by the write-off of acquired in-process research and development related to the Merck Generics acquisition and the acquisition of the controlling interest in Matrix.

Transition Period Ended December 31, 2007 Compared to Nine-Month Period Ended December 31, 2006

As noted above, transition period refers to the nine-month period from April 1, 2007 through December 31, 2007. In the discussion that follows, comparable nine-month period or prior period refers to the nine-month period from April 1, 2006 through December 31, 2006.

Total Revenues and Gross Profit

For the transition period, Mylan reported total revenues of $2.18 billion compared to $1.12 billion in the comparable nine-month period. This represents an increase of $1.05 billion or 94%. The acquisition of the former Merck Generics business contributed revenues of $700.6 million, of which $598.5 million are included in the Generics Segment and $102.1 million are included in the Specialty Segment. Matrix contributed revenues of $264.2 million, all of which are included in the Generics Segment, and are incremental in the period ended December 31, 2007. The remaining increase is primarily due to growth in Mylan s historical business.

Other revenue for the transition period was $15.8 million compared to $21.3 million in the comparable nine-month period. The decrease is primarily the result of the recognition, in the prior period, of previously deferred amounts related to the sale of Apokyn®, which was fully recognized by December 31, 2006.

In arriving at net revenues, gross revenues are reduced by provisions for estimates, including discounts, customer performance and promotions, price adjustments, returns and chargebacks. See the section titled *Application of Critical Accounting Policies* in this Item 7, for a thorough discussion of our methodology with respect to such provisions. For the transition period, the most significant amounts charged against gross revenues were for chargebacks in the amount of $1.01 billion and customer performance and promotions in the amount of $199.7 million. For the comparable nine-month period, chargebacks of $893.3 million and customer performance and promotions of $122.9 million were charged against gross revenues. Customer performance and promotions include direct rebates as well as promotional programs.

Gross profit for the transition period was $874.4 million and gross margins were 40.1%. Gross profit is impacted by certain purchase accounting related items recorded during the nine months ended December 31, 2007 of

approximately $148.9 million, which consisted primarily of incremental amortization related to purchased intangible assets and the amortization of the inventory step-up associated with the acquisition of both the former Merck Generics business and Matrix. Excluding such items, gross margins were 47.0% compared to 54.1% for the nine months ended December 31, 2006.

A significant portion of gross profit in the transition period, excluding amounts related to the acquisitions of the former Merck Generics business and Matrix, was comprised of fentanyl and new products, including amlodipine. Products generally contribute most significantly to gross margin at the time of their launch and

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even more so in periods of market exclusivity or limited generic competition. As a result of multiple market entrants shortly after Mylan s launch of amlodipine, Mylan did not realize all of the benefits of market exclusivity (less than 180 days) with respect to this product. As it relates to fentanyl, additional competitors entered the market during the current period which had a negative impact on pricing and volume. Additionally, the companies acquired during the period have lower overall gross margins, and, as such, Mylan s consolidated gross margin was also unfavorably impacted by this incremental revenue and gross profit.

Generics Segment

For the transition period, the Generics Segment reported total revenues of $2.08 billion. Revenues from North America were $1.27 billion for the transition period compared to $1.12 billion for the comparable nine-month period, representing an increase of $143.8 million or 13%. Of this increase, $54.4 million is the result of the acquisition of the former Merck Generics business. Excluding the impact of the acquisition, total North America revenues increased by $89.4 million or 8%. This increase is the result of new products and favorable volume, partially offset by unfavorable pricing.

Products launched subsequent to December 31, 2006, contributed net revenues of $156.5 million, the majority of which was amlodipine. Fentanyl, Mylan s AB-rated generic alternative to Duragesic, continued to contribute significantly to the financial results, accounting for nearly 10% of Generics Segment net revenues despite the entrance into the market of additional generic competition in August 2007. As expected, the additional competition had an unfavorable impact on fentanyl pricing. Additional generic competition, as well as the impact of continued consolidation among retail customers, negatively impacted pricing on other products in our portfolio. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products.

Doses shipped during the transition period, excluding the impact of acquisitions, increased by over 15% to 11.8 billion.

Revenues from EMEA were $460.9 million for the transition period, the majority of which was the result of the acquisition of the former Merck Generics business. Also included within EMEA for the transition period are revenues from the distribution of branded generic products in Europe through a wholly-owned subsidiary of Matrix.

Revenues from Asia Pacific were $376.9 million for the transition period, $170.9 million of which were the result of the acquisition of the former Merck Generics business and $206.0 million of which were the result of the acquisition of Matrix.

Specialty Segment

For the transition period, the Specialty Segment reported total third-party revenues of $102.1 million. The Specialty Segment consists primarily of Dey, an entity acquired as part of the former Merck Generics business acquisition that focuses on the development, manufacturing and marketing of specialty pharmaceuticals in the respiratory and severe allergy markets. The majority of the Specialty Segment revenues are derived from two products; DuoNeb® and EpiPen Auto-injector.

DuoNeb is a nebulized unit dose formulation of ipratropium bromide and albuterol sulfate for treatment of chronic obstructive pulmonary disorder. DuoNeb lost exclusivity in July 2007, at which time generic competition entered the market. The impact on sales of the generic competition was not as significant as expected during the transition period, however, sales did subsequently decline significantly as a result of the additional competition.

EpiPen Auto-injector, which is used in the treatment of severe allergies, is an epinephrine auto-injector. EpiPen Auto-injector is the number one prescribed treatment for severe allergic reactions. Prescriptions for EpiPen Auto-injector have continued to grow and during the quarter ended December 31, 2007, have reached the highest prescription volume in the history of the brand.

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Operating Expenses

Research and development expense for the transition period was $146.1 million compared to $66.8 million in the comparable nine-month period. Transition period R&D includes approximately $71.2 million related to newly acquired entities, all of which was incremental to the comparable nine-month period. Excluding these amounts, R&D expense increased by $8.1 million or 12% as a result of increased clinical studies and higher R&D headcount related to a higher level of ANDA submission activity.

Additionally, during the nine months ended December 31, 2007, we recognized a charge of $1.27 billion to write-off acquired in-process R&D associated with the former Merck Generics business acquisition. This amount represents the fair value of purchased in-process technology for research projects that, as of the closing date of the acquisition, had not reached technological feasibility and had no alternative future use.

The acquisition of the former Merck Generics business and Matrix added $201.8 million of incremental selling, general and administrative expense to the current period. Excluding this amount, SG&A expense increased by $95.1 million or 62% to $247.8 million compared to $152.8 million in the comparable nine-month period. The majority of this increase was realized by Corporate/Other.

The increase in Corporate/Other SG&A expense is due to an increase of approximately $60.0 million in both professional and consulting fees and payroll and related expenses, with the remainder due primarily to higher temporary services and depreciation. The increase in professional and consulting fees and temporary services is associated primarily with the integration of the former Merck Generics business. The increase in payroll and related costs is principally attributable to the build-up of additional corporate infrastructure as a direct result of the former Merck Generics business acquisition.

Litigation, net

Litigation settlements, net, in the transition period yielded income of $2.0 million compared to income of $46.2 million in the comparable nine-month period. These amounts are both due to the favorable settlement of outstanding litigation in the respective periods.

Interest Expense

Interest expense for the transition period totaled $196.3 million compared to $31.3 million for the nine months ended December 31, 2006. The increase is due to the additional debt incurred to finance the acquisition of the former Merck Generics business. See *Liquidity and Capital Resources* for further discussion.

Other Income, net

Other income, net was income of $86.6 million in the transition period compared to $39.8 million in the comparable nine-month period. The most significant items in the current period are net foreign exchange gains consisting mainly of $85.0 million on a contract related to the acquisition of the former Merck Generics business and a loss of $57.2 million on the early repayment of certain debt and expensing certain financing fees, with the remainder of the other income attributable to interest and dividends. As the purpose of the foreign currency option contract was to mitigate exchange rate risk on the Euro-denominated purchase price, the settlement of this contract was included in current earnings.

The $57.2 million loss relates to a tender offer made to holders of our Senior Notes and financing fees related to the Interim Term Loan. As part of its strategy to establish a new global capital structure related to the acquisition of the

former Merck Generics business, Mylan refinanced its debt, including making a tender offer to holders of its Senior Notes. Included as part of this tender was a premium to holders of the Senior Notes in the amount of $30.8 million. In addition to this premium, approximately $12.1 million of deferred financing fees were written off and approximately $14.3 million for financing fees related to the Interim Term Loan were incurred.

In the comparable nine-month period, we recorded a net gain of $17.5 million related to a foreign currency forward contract for the acquisition of Matrix. The remainder of the net other income realized in the prior period is the result of interest and dividend income and a $5.0 million payment received from an investee accounted for using the equity method in excess of its carrying amount.

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Income Tax Expense

Our provision for income taxes was $53.4 million in the nine-month period ending December 31, 2007 as compared to $155.3 million in the nine-month period ending December 31, 2006. The decrease in tax expense is attributable to a reduction in operating income, before the acquired in-process R&D charge, of $255.9 million. The effective tax rate was impacted by the $1.27 billion non-deductible charge related to in-process R&D acquired as part of the Merck transaction. The effective tax rate in 2007 was (4.9%) as compared to 35.0% for the comparable nine-month period in 2006.

Liquidity and Capital Resources

Our primary source of liquidity is cash provided by operations, which were $605.1 million for the year ended December 31, 2009. Included in this amount was a net after-tax cash outflow of approximately $52.0 million related to the settlement of an investigation by the U.S. Department of Justice discussed above. We believe that cash provided by operating activities will continue to allow us to meet our needs for working capital, capital expenditures, interest and principal payments on debt obligations, dividend payments and other cash needs over the next several years. Nevertheless, our ability to satisfy our working capital requirements and debt service obligations, or fund planned capital expenditures, will substantially depend upon our future operating performance (which will be affected by prevailing economic conditions), and financial, business and other factors, some of which are beyond our control.

We prepare our statement of cash flows using the indirect method. Under this method, we reconcile net income to cash flows from operating activities by adjusted net income for those items that impact net income but may not result in actual cash receipts or payments during the period. These reconciling items include depreciation and amortization, deferred income taxes, changes in estimated sales allowances, litigation settlements and changes in the consolidated balance sheet for working capital from the beginning to the end of the period.

Working capital at December 31, 2009 was $1.57 billion compared to $1.63 billion at December 31, 2008, a decrease of $6.0 million, which includes the effect of foreign exchange. Excluding foreign exchange translation, increased working capital requirements during 2009 had an unfavorable impact on operating cash flows. This is due mainly to payments made for income taxes, and increased accounts receivable, primarily due to the timing of cash collections and the level of sales near the end of the period.

In the prior year, working capital requirements also negatively impacted cash from operations, with increases in accounts receivable and inventory partially offset by increases in both accounts payable and accrued taxes payable.

Cash used in investing activities was $335.0 million for calendar year 2009, driven primarily by cash paid for acquisitions and capital expenditures. Cash paid for acquisitions was $187.4 million, net, consisting primarily of a cash outflow of approximately $182.2 million related to the acquisition of the remaining interest of Matrix. During 2009, several other transactions were completed including the sale of a 50% interest in a joint venture, the purchase of the remaining 50% interest in a separate joint venture in which Matrix previously held a 50% stake, the sale of a majority-owned subsidiary by Matrix to the minority owner and the purchase of an API facility in India. These transactions resulted in a net cash outflow of $5.3 million.

Capital expenditures were $154.4 million, and were made primarily for equipment, including a portion related to our previously announced planned expansions and integration plans surrounding the former Merck Generics business. Capital expenditures for 2010 are expected to increase to approximately $250.0 million.

Cash used in financing activities was $454.4 million for calendar year 2009. During 2009, we made repayments on our long-term debt in the amount of $350.0 million, consisting primarily of prepayments on Senior Credit Agreement

amounts due in 2010 and 2011. Additionally, we paid cash dividends of $139.0 million on our 6.5% mandatory convertible preferred stock.

We are involved in various legal proceedings that are considered normal to its business. While it is not possible to predict the outcome of such proceedings, an adverse outcome in any of these proceedings could materially affect

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our financial position and results of operations. Additionally, for certain contingencies assumed in conjunction with the acquisition of the former Merck Generics business, Merck KGaA, the seller, has indemnified Mylan under the provisions of the Share Purchase Agreement. The inability or denial of Merck KGaA to pay on an indemnified claim, could have a material adverse effect on our financial position or results of operations.

Our Consolidated Balance Sheet as of December 31, 2009 includes restructuring reserves of $39.3 million. Spending against this balance, which consists primarily of severance and related costs and costs associated with the previously announced rationalization and optimization of our global manufacturing and research and development platforms, is expected to occur over the next one to two years, with the majority in 2010.

On May 7, 2009, at the annual shareholders meeting, our shareholders approved an increase in the number of authorized shares of Mylan s common stock from 600,000,000 to 1,500,000,000. In addition, the shareholders approved an increase in shares that may be issued under our 2003 Long-Term Incentive Plan as restricted shares, restricted units, performance shares and other stock-based awards from 5,000,000 to 8,000,000.

During and subsequent to 2009, we declared quarterly dividends on our preferred stock of $16.25, based on the annual dividend rate of 6.5% and a liquidation preference of $1,000 per share, as follows:

Date Declared:	Date Payable:	To Holders of Preferred Stock of Record As of:
January 29, 2009	February 17, 2009	February 1, 2009
April 16, 2009	May 15, 2009	May 1, 2009
July 20, 2009	August 17, 2009	August 1, 2009
October 20, 2009	November 16, 2009	November 1, 2009
January 10, 2010	February 16, 2010	February 1, 2010

Total dividends declared and paid during calendar year 2009 were $139.0 million.

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

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

At December 31, 2009 and December 31, 2008, we had $77.5 million and $83.6 million outstanding under existing letters of credit. Additionally, as of December 31, 2009, we had $44.3 million available under the $100.0 million subfacility on our Senior Credit Agreement for the issuance of letters of credit.

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Mandatory minimum repayments remaining on the outstanding borrowings under the term loans and convertible notes at December 31, 2009, excluding the discounts and conversion features, are as follows for each of the periods ending December 31:

(In thousands)	U.S. Tranche A Term Loans	Euro Tranche A Term Loans	U.S. Tranche B Term Loans	Euro Tranche B Term Loans	Senior Convertible Notes	Cash Convertible Notes	Total
2010	$	$	$	$	$	$	$
2011							
2012	78,125	126,149	25,560	7,560	600,000		837,394
2013	78,125	126,149	25,560	7,560			237,394
2014			2,402,640	710,640			3,113,280
2015						575,000	575,000
Total	$ 156,250	$ 252,298	$ 2,453,760	$ 725,760	$ 600,000	$ 575,000	$ 4,763,068

The Senior Credit Agreement contains customary affirmative covenants for facilities of this type, including covenants pertaining to the delivery of financial statements, notices of default and certain other information, maintenance of business and insurance, collateral matters and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of indebtedness and liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, dispositions of assets, payments of dividends and other restricted payments, prepayments or amendments to the terms of specified indebtedness (including the Interim Credit Agreement described below) and changes in lines of business. The Senior Credit Agreement contains financial covenants requiring maintenance of a minimum interest coverage ratio and a senior leverage ratio, both of which are defined within the agreement. We have been compliant with the financial covenants during the calendar year ended December 31, 2009.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2009 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

(in thousands)	Total	Less than One Year	One-Three Years	Three-Five Years	Thereafter
Operating leases	$ 157,849	$ 30,334	$ 41,877	$ 22,466	$ 63,172
Total debt	4,780,506	6,348	845,884	3,353,092	575,182
Scheduled interest payments	709,950	159,092	310,026	219,263	21,569
Preferred dividends	139,035	139,035			
	$ 5,787,340	$ 334,809	$ 1,197,787	$ 3,594,821	$ 659,923

The chart above does not include short-term borrowings held by Matrix in the amount of approximately $184.3 million, which represent working capital facilities with several banks, which are secured first by Matrix s current assets and second by Matrix s property, plant and equipment and carry interest rates of 4.0%-14.5%. Additionally, due to the uncertainty with respect to the timing of future cash flows associated with our unrecognized tax benefits at December 31, 2009, we are unable to make reasonably reliable estimates of the period of cash settlement with the respective taxing authority. As such, $237.5 million of unrecognized tax benefits have been excluded from the contractual obligations table above.

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

Total debt consists of the U.S. Tranche A Term Loans of $156.3 million, the Euro Tranche A Term Loans of 175.2 ($252.3) million, the U.S. Tranche B Term Loans of $2.45 billion, the Euro Tranche B Term Loans of 504.0

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($725.8) million, $600.0 million in the nominal value of the Senior Convertible Notes, $575.0 million in the nominal value of the Cash Convertible Notes and $17.4 million of other miscellaneous debt.

At December 31, 2009, the $847.1 million of debt related to the Cash Convertible Notes reported in our financial statements consists of $436.5 million of debt ($575.0 million face amount, net of $138.5 million discount) and a liability with a fair value of $410.6 million related to the bifurcated conversion feature.

As of December 31, 2009, the $575.0 million of Cash Convertible Notes was currently convertible. Although the Company s experience is that convertible debentures are not normally converted by investors until close to their maturity date, it is possible that debentures could be converted prior to their maturity date if, for example, a holder perceives the market for the debentures to be weaker than the market for the common stock. Upon an investor s election to convert, the Company is required to pay the full conversion value in cash. Any payment above the principal amount is matched by a convertible note hedge as described below. Should holders elect to convert, the Company intends to draw on its revolving credit facility to fund any principal payments. The facility is an unsecured revolving credit agreement expiring in October 2013, with available capacity of $694.3 million at December 31, 2009.

Scheduled interest payments represent the estimated interest payments on the U.S. Tranche A Term Loans, the Euro Tranche A Term Loans, the U.S. Tranche B Term Loans, the Euro Tranche B Term Loans, the Senior Convertible Notes, the Cash Convertible Notes and other debt. Variable debt interest payments are estimated using current interest rates.

We have entered into various product licensing and development agreements. In some of these arrangements, we provide funding for the development of the product or to obtain rights to the use of the patent, through milestone payments, in exchange for marketing and distribution rights to the product. Milestones represent the completion of specific contractual events, and it is uncertain if and when these milestones will be achieved, hence, we have not attempted to predict the period in which such milestones would possibly be incurred. In the event that all projects are successful, milestone and development payments of approximately $33.8 million would be paid subsequent to December 31, 2009.

The Company has entered into an exclusive collaboration on the development, manufacturing, supply and commercialization of multiple, high value generic biologic compounds for the global marketplace. Mylan has committed to provide funding related to the collaboration over the next several years and amounts could be substantial.

Additionally, we have entered into product development agreements under which we have agreed to share in the development costs as they are incurred by our partners. As the timing of cash expenditures is dependent upon a number of factors, many of which are outside of our control, it is difficult to forecast the amount of payments to be made over the next few years, which could be significant.

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

The Company sponsors various defined benefit pension plans in several countries. Benefit formulas are based on varying criteria on a plan by plan basis. The Company funds non-domestic pension liabilities in accordance with laws and regulations applicable to those plans, which typically results in these plans being unfunded. The amount accrued related to these benefits was $50.9 million at December 31, 2009. We are unable to determine when these amounts will require payment as the timing of cash expenditures is dependent upon a number of factors, many of which are outside of our control

We have entered into employment and other agreements with certain executives and other employees that provide for compensation and certain other benefits. These agreements provide for severance payments under certain circumstances.

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Impact of Currency Fluctuations and Inflation

Because Mylan s results are reported in U.S. Dollars, changes in the rate of exchange between the U.S. Dollar and the local currencies in the markets in which Mylan operates, mainly the Euro, Australian Dollar, Indian Rupee, Japanese Yen, Canadian Dollar, and Pound Sterling, affect Mylan s results.

Application of Critical Accounting Policies

Our significant accounting policies are described in Note 2 to Consolidated Financial Statements, which were prepared in accordance with accounting principles generally accepted in the United States of America (GAAP).

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

Net Revenue Provisions

Net revenues are recognized for product sales when title and risk of loss have transferred to the customer and when provisions for estimates, including discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks and other potential adjustments are reasonably determinable. Accruals for these provisions are presented in the Consolidated Financial Statements as reductions in determining net revenues and in accounts receivable and other current liabilities. Accounts receivable are presented net of allowances relating to these provisions, which were $607.9 million and $496.5 million at December 31, 2009 and December 31, 2008. Other current liabilities include $238.2 million and $238.9 million at December 31, 2009 and December 31, 2008, for certain rebates and other adjustments that are paid to indirect customers. The following is a rollforward of the most significant provisions for estimated sales allowances during calendar year 2009:

(in thousands)	**Balance at 12/31/2008**	**Checks/Credits Issued to Third Parties**	**Current Provision Related to Sales Made in the Current Period**	**Effects of Foreign Exchange**	**Balance at 12/31/2009**
Chargebacks	$ 173,213	$ (1,824,957)	$ 1,894,090	$ 376	$ 242,722
Promotions and indirect rebates	$ 330,832	$ (1,028,135)	$ 1,081,590	$ 15,246	$ 399,533
Returns	$ 81,295	$ (66,408)	$ 73,160	$ 1,684	$ 89,731

The accrual for chargebacks increased as a result of numerous factors including the addition of accruals for significant new products launched during the year and a shift in product mix in the U.S. to products with high volume sales and high chargeback rates.

Provisions for estimated discounts, rebates, promotional and other credits require a lower degree of subjectivity and are less complex in nature yet, combined, represent a significant portion of the overall provisions. These provisions are estimated based on historical payment experience, historical relationships to revenues, estimated customer inventory levels and contract terms. Such provisions are determinable due to the limited number of assumptions and consistency of historical experience. Others, such as returns and chargebacks, require management to make more subjective judgments and evaluate current market conditions. These provisions are discussed in further detail below.

Returns Consistent with industry practice, we maintain a return policy that allows our customers to return product within a specified period prior to and subsequent to the expiration date. Although application of the policy varies from country to country in accordance with local practices, generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. The majority of our product returns occur as a result of product dating, which falls within the range set by our policy, and are settled

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through the issuance of a credit to our customer. Although the introduction of additional generic competition does not give our customers the right to return product outside of our established policy, we do recognize that such competition could ultimately lead to increased returns. We analyze this on a case-by-case basis, when significant, and make adjustments to increase our reserve for product returns as necessary. Our estimate of the provision for returns is based upon our historical experience with actual returns, which is applied to the level of sales for the period that corresponds to the period during which our customers may return product. This period is known by us based on the shelf lives of our products at the time of shipment. Additionally, we consider factors such as levels of inventory in the distribution channel, product dating, and expiration period, size and maturity of the market prior to a product launch, entrance into the market of additional generic competition, changes in formularies or launch of over-the-counter products, and make adjustments to the provision for returns in the event that it appears that actual product returns may differ from our established reserves. We obtain data with respect to the level of inventory in the channel directly from certain of our largest customers. A change of 5% in the estimated product return rate used in our calculation of our return reserve would have an effect on our reserve balance of approximately $4.5 million.

Chargebacks The provision for chargebacks is the most significant and complex estimate used in the recognition of revenue. The Company markets products directly to wholesalers, distributors, retail pharmacy chains, mail order pharmacies and group purchasing organizations. The Company also markets products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and pharmacy benefit management companies, collectively referred to as indirect customers. Mylan enters into agreements with its indirect customers to establish contract pricing for certain products. The indirect customers then independently select a wholesaler from which to actually purchase the products at these contracted prices. Alternatively, certain wholesalers may enter into agreements with indirect customers that establish contract pricing for certain products, which the wholesalers provide. Under either arrangement, Mylan will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler s invoice price. Such credit is called a chargeback, while the difference between the contracted price and the wholesaler s invoice price is referred to as the chargeback rate. The provision for chargebacks is based on expected sell-through levels by our wholesaler customers to indirect customers, as well as estimated wholesaler inventory levels. For the latter, in most cases, inventory levels are obtained directly from certain of our largest wholesalers. Additionally, internal estimates are prepared based upon historical buying patterns and estimated end-user demand. Such information allows us to estimate the potential chargeback that we may ultimately owe to our customers given the quantity of inventory on hand. We continually monitor our provision for chargebacks and evaluate our reserve and estimates as additional information becomes available. A change of 5% in the estimated sell-through levels by our wholesaler customers and in the estimated wholesaler inventory levels would have an effect on our reserve balance of approximately $12.0 million.

While we do not anticipate any significant changes to the methodologies that we use to measure chargebacks, customer performance and promotions or returns, the balances within these reserves can fluctuate significantly through the consistent application of our methodologies. Historically, we have not recorded in any current period any material amounts related to adjustments made to prior period reserves. Should any material amounts from any prior period be recorded in any current period such amounts will be disclosed.

Intangible Assets and Goodwill

We account for acquired businesses using the purchase method of accounting, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The cost to acquire a business has been allocated to the underlying net assets of the acquired business based on estimates of their respective fair values. Amounts allocated to acquired in-process research and development (IPR&D) had been expensed at the date of acquisition, but will be capitalized going forward. Intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. Because this process involves management making estimates

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with respect to future sales volumes, pricing, new product launches, anticipated cost environment and overall market conditions and because these estimates form the basis for the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

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

As discussed above with respect to determining an asset s fair value and useful life, because this process involves management making certain estimates and because these estimates form the basis for the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates. The Company will continue to assess the carrying value of its goodwill and intangible assets in accordance with applicable accounting guidance.

Income Taxes

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

The Company records valuation allowances to reduce deferred tax assets to the amount that is more likely than not to be realized. When assessing the need for valuation allowances, the Company considers future taxable income and ongoing prudent and feasible tax planning strategies. Should a change in circumstances lead to a change in judgment about the realizability of deferred tax assets in future years, the Company would adjust related valuation allowances in the period that the change in circumstances occurs, along with a corresponding increase or charge to income taxes.

The resolution of tax reserves and changes in valuation allowances could be material to the Company s results of operations or financial position. A variance of 5% between estimated reserves and actual resolution and realization of tax items would have an effect on our reserve balance of approximately $20.0 million.

Legal Matters

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

A variance of 5% between estimated and recorded litigation reserves (excluding indemnified claims) and actual resolution of certain legal matters would have an effect on our litigation reserve balance of approximately $10.0 million.

Recent Accounting Pronouncements

In May 2008, the FASB issued guidance about accounting for convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement), which was adopted by the Company on January 1, 2009.

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Under the new rules, for convertible debt instruments (including the Company s Senior Convertible Notes) that may be settled entirely or partially in cash upon conversion, entities now separately account for the liability and equity components of the instrument in a manner that reflects the issuer s economic interest cost. The effect of the new rules, as they apply to the Company s Senior Convertible Notes, is that the equity component is included in the additional paid-in capital section of shareholders equity on the Company s consolidated balance sheet and the value of the equity component is treated as an original issue discount for purposes of accounting for the debt component. Higher interest expense results through the accretion of the discounted carrying value of the Senior Convertible Notes to their face amount over their term. This update requires retrospective application as disclosed below.

In December 2007, the FASB issued guidance regarding noncontrolling interests in consolidated financial statements, which was adopted by the Company on January 1, 2009. This update amends previously issued guidance, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This standard defines a noncontrolling interest, sometimes called a minority interest, as the portion of equity in a subsidiary not attributable, directly or indirectly, to a parent. This update requires, among other items, that a noncontrolling interest be included in the consolidated balance sheet within equity separate from the parent s equity; consolidated net income to be reported at amounts inclusive of both the parent s and noncontrolling interest s shares and, separately, the amounts of consolidated net income attributable to the parent and noncontrolling interest all on the consolidated statement of operations; and if a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary be measured at fair value and a gain or loss be recognized in net income based on such fair value.

The Company s Consolidated Statements of Operations for the calendar year ended December 31, 2008 and the nine months ended December 31, 2007, as originally reported and as adjusted for the adoption of the aforementioned updates related to convertible debt instruments and noncontrolling interests, are as follows:

	Calendar Year Ended December 31,		Nine Months Ended December 31,	
(in thousands, except per share amounts)	2008	2008 As Adjusted	2007	2007 As Adjusted
Interest expense	$ 357,045	$ 380,779	$ 179,410	$ 196,335
Loss before income taxes and noncontrolling interest	(47,823)	(71,557)	(1,081,064)	(1,097,989)
Income tax provision	137,423	128,550	60,073	53,413
Net loss	(185,246)	(200,107)	(1,141,137)	(1,151,402)
Net loss attributable to the noncontrolling interest	4,031	4,031	3,112	3,112
Net loss attributable to Mylan Inc. common shareholders	(320,250)	(335,111)	(1,154,024)	(1,164,289)
Loss per common share attributable to Mylan Inc.:				
Basic	$ (1.05)	$ (1.10)	$ (4.49)	$ (4.53)
Diluted	$ (1.05)	$ (1.10)	$ (4.49)	$ (4.53)
Weighted average common shares outstanding:				
Basic	304,360	304,360	257,150	257,150
Diluted	304,360	304,360	257,150	257,150

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The Company s Consolidated Balance Sheet, as originally reported and as adjusted for the adoption of the aforementioned updates related to convertible debt instruments and non controlling interests, is as follows:

(in thousands)	**December 31, 2008**	**December 31, 2008 As Adjusted**
Liabilities and equity		
Liabilities		
Long-term debt	$ 5,165,419	$ 5,078,937
Deferred income tax liability	545,121	577,379
Total liabilities	7,677,242	7,623,018
Minority interest	29,108	
Equity		
Mylan Inc. shareholders equity		
Additional paid-in capital	3,873,743	3,955,725
Retained earnings	594,352	566,594
Noncontrolling interest		29,108
Total equity	2,703,509	2,786,841

In October 2009, the FASB issued revised accounting guidance for multiple-deliverable arrangements. The amendment requires that arrangement considerations be allocated at the inception of the arrangement to all deliverables using the relative selling price method and provides for expanded disclosures related to such arrangements. It is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

The Company is subject to market risk from changes in foreign currency exchange rates and interest rates. In conjunction with the acquisition of the former Merck Generics business in 2007, Mylan s exposure to these areas was materially increased. The Company now manages these increased financial exposures through operational means and by using various financial instruments. These practices may change as economic conditions change.

In conjunction with the acquisition of the former Merck Generics business, the Company incurred substantial indebtedness, most of which has variable interest rates (see *Liquidity and Capital Resources*) and the Company became subjected to increased foreign currency exchange risk.

Foreign Currency Exchange Risk

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

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

In addition, the Company protects against possible declines in the reported net assets of Mylan s Euro functional-currency subsidiaries through the use of Euro denominated debt.

In conjunction with the Matrix transaction in 2007, the Company entered into a deal-contingent foreign exchange forward contract to purchase Indian Rupees with U.S. Dollars in order to mitigate the risk of foreign currency exposure related to the Indian Rupee-denominated purchase price. In conjunction with the acquisition of the former Merck Generics business in 2007, Mylan entered into a deal-contingent foreign currency option contract in order to mitigate the risk of foreign currency exposure related to the Euro-denominated purchase price. The instruments did not qualify for hedge accounting treatment and therefore were required to be adjusted to fair value with the change in the fair value of the instrument recorded in current earnings.

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

foreign currency forward-exchange contracts net present values

foreign currency denominated receivables, payables, debt and loans changes in exchange rates

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

If there were an adverse change in foreign currency exchange rates of 10%, the expected net effect on net income related to Mylan s foreign currency denominated financial instruments would be immaterial.

Interest Rate and Long-Term Debt Risk

Mylan s exposure to interest rate risk arises primarily from our U.S. Dollar and Euro borrowings and investments. The Company invests primarily on a variable-rate basis. Mylan borrows on both a fixed and variable basis. From time to time, depending on market conditions, Mylan will fix interest rates on variable-rate borrowings through the use of derivative financial instruments such as interest rate swaps.

Mylan s long-term borrowings consist principally of $2.61 billion in U.S. dollar denominated loans and $978.1 million in Euro denominated debt under our Senior Credit Agreement, $538.7 million in Senior Convertible Notes and $847.1 million in Cash Convertible Notes.

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Generally, the fair value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. The fair value of the Senior Convertible Notes and the Cash Convertible Notes will fluctuate as the market value of our common stock fluctuates. As of December 31, 2009, the fair value of our Senior Convertible Notes was approximately $612.8 million and the fair value of Mylan s Cash Convertible Notes was approximately $879.8 million. A 100 basis point change in interest rates on the variable rate debt, net of interest rate swaps, would result in a change in interest expense of approximately $15 million per year.

Investments

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

The marketable equity securities are not material for the periods ended December 31, 2009 or 2008. The primary objectives for the available-for-sale securities investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return while retaining principal. Our investment policy limits investments to certain types of instruments issued by institutions and government agencies with investment grade credit ratings. At December 31, 2009, the Company had invested $26.5 million in available-for-sale fixed income securities, of which $0.3 million will mature within one year and $26.2 million will mature after one year. The short duration to maturity creates minimal exposure to fluctuations in fair values for investments that will mature within one year. However, a significant change in current interest rates could affect the fair value of the remaining $26.2 million of available-for-sale securities that mature after one year. An approximate 5% adverse change in interest rates on available-for-sale securities that mature after one year would result in a decrease of approximately $1.0 million in the fair value of available-for-sale securities.

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ITEM 8. Financial Statements and Supplementary Data

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MYLAN INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 380,516	$ 557,147
Restricted cash	47,965	40,309
Available-for-sale securities	27,559	42,260
Accounts receivable, net	1,234,634	1,164,613
Inventories	1,114,219	1,065,990
Deferred income tax benefit	248,917	199,278
Prepaid expenses and other current assets	231,576	105,076
Total current assets	3,285,386	3,174,673
Property, plant and equipment, net	1,122,648	1,063,996
Intangible assets, net	2,384,848	2,453,161
Goodwill	3,331,247	3,161,580
Deferred income tax benefit	36,610	16,493
Other assets	640,995	539,956
Total assets	$ 10,801,734	$ 10,409,859
Liabilities and equity		
Liabilities		
Current liabilities:		
Trade accounts payable	$ 518,252	$ 498,815
Short-term borrowings	184,352	151,109
Income taxes payable	69,122	92,158
Current portion of long-term debt and other long-term obligations	9,522	5,099
Deferred income tax liability	1,986	1,935
Other current liabilities	934,913	795,534
Total current liabilities	1,718,147	1,544,650
Long-term debt	4,984,987	5,078,937
Other long-term obligations	485,905	422,052
Deferred income tax liability	467,497	577,379
Total liabilities	7,656,536	7,623,018
Equity		
Mylan Inc. shareholders equity		
Preferred stock par value $0.50 per share		
Shares authorized: 5,000,000		
Shares issued: 2,139,000	1,070	1,070

Common stock par value $0.50 per share Shares authorized: 1,500,000,000 and 600,000,000 as of December 31, 2009 and December 31, 2008 Shares issued: 396,683,892 and 395,368,062 as of December 31, 2009 and December 31, 2008		198,342		197,684
Additional paid-in capital		3,834,674		3,955,725
Retained earnings		660,130		566,594
Accumulated other comprehensive earnings (loss)		11,807		(380,802)
		4,706,023		4,340,271
Noncontrolling interest		14,052		29,108
Less treasury stock at cost Shares: 90,199,152 and 90,635,441 as of December 31, 2009 and December 31, 2008		1,574,877		1,582,538
Total equity		3,145,198		2,786,841
Total liabilities and equity	$	10,801,734	$	10,409,859

See Notes to Consolidated Financial Statements

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

	Calendar Year Ended December 31, 2009	Calendar Year Ended December 31, 2008	Nine Months Ended December 31, 2007
Revenues:			
Net revenues	$ 5,015,394	$ 4,631,237	$ 2,162,943
Other revenues	77,391	506,348	15,818
Total revenues	5,092,785	5,137,585	2,178,761
Cost of sales	3,018,313	3,067,364	1,304,313
Gross profit	2,074,472	2,070,221	874,448
Operating expenses:			
Research and development	275,258	317,217	146,063
Acquired in-process research and development			1,269,036
Goodwill impairment		385,000	
Selling, general and administrative	1,050,145	1,053,485	449,598
Litigation settlements, net	225,717	16,634	(1,984)
Total operating expenses	1,551,120	1,772,336	1,862,713
Earnings (loss) from operations	523,352	297,885	(988,265)
Interest expense	318,496	380,779	196,335
Other income, net	22,119	11,337	86,611
Earnings (loss) before income taxes and noncontrolling interest	226,975	(71,557)	(1,097,989)
Income tax (benefit) provision	(20,773)	128,550	53,413
Net earnings (loss)	247,748	(200,107)	(1,151,402)
Net (earnings) loss attributable to the noncontrolling interest	(15,177)	4,031	3,112
Net earnings (loss) attributable to Mylan Inc. before preferred dividends	232,571	(196,076)	(1,148,290)
Preferred dividends	139,035	139,035	15,999
Net earnings (loss) attributable to Mylan Inc. common shareholders	$ 93,536	$ (335,111)	$ (1,164,289)
Earnings (loss) per common share attributable			.

to Mylan Inc. common shareholders:			
Basic	$ 0.31	$ (1.10)	$ (4.53)
Diluted	$ 0.30	$ (1.10)	$ (4.53)
Weighted average common shares outstanding:			
Basic	305,162	304,360	257,150
Diluted	306,913	304,360	257,150

See Notes to Consolidated Financial Statements

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MYLAN INC. AND SUBSIDIARIES
Consolidated Statements of Equity and Comprehensive Earnings (Loss)
(In thousands, except share and per share amounts)

ensive ngs s)	Preferred Stock Shares	Preferred Stock Cost	Common Stock Shares	Common Stock Cost	Additional Paid-In Capital	Retained Earnings	Treasury Stock Shares	Treasury Stock Cost	C
			339,361,201	169,681	1,044,728	2,100,958	(90,948,957)	(1,588,393)	
1,402)						(1,148,290)			
(663)									
7,602									
4,723)									
(716)									
1,500									
9,902)									
3,112									
6,790)									
			55,440,000	27,720	720,331				
			459,154	229	7,503				

	2,139,000	1,070			2,072,816			
					(1,485)		63,769	1,489
					17,332			
					5,648			
						(11,478)		
						(15,999)		
						(14,923)		
					838	(324)		
	2,139,000	1,070	395,260,355	197,630	3,867,711	909,944	(90,885,188)	(1,586,904)
0,107)						(196,076)		
2,529)								
0,167)								
0,633)								
(517)								
3,846)								

,953)

,275

,678)

		107,707	54	1,137				
				(5,529)		249,747	4,366	
				30,639				
				(223)				
				62,560				
					(8,255)			
					(139,035)			
				(570)	16			
2,139,000	$ 1,070	395,368,062	$ 197,684	$ 3,955,725	$ 566,594	(90,635,441)	$ (1,582,538)	

See Notes to Consolidated Financial Statements

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MYLAN INC. AND SUBSIDIARIES
Consolidated Statements of Equity and Comprehensive Earnings (Loss) (Continued)
(In thousands, except share and per share amounts)

	Comprehensive Earnings (Loss)	Preferred Stock Shares	Preferred Stock Cost	Common Stock Shares	Common Stock Cost	Additional Paid-In Capital	Retained Earnings	Treasury Stock Shares	Treasury Stock Cost	Accumulated Other Comprehensive Earnings	Noncontrolling Interest	Tota Equi
arnings	$ 247,748						232,571				15,177	247,
ge in unrecognized s and prior service												
d to post-retirement , net of tax	1,471									1,471		1,
gn currency lation adjustment	384,218									384,220	(2)	384,
nrecognized losses rivatives, net of tax	6,134									6,134		6,
nrealized loss gain arketable securities, f tax	614											
assification for gains s included in net ngs	170	784								784		
r comprehensive ngs	392,607											
prehensive earnings	640,355											
prehensive earnings utable to the ontrolling interest	(15,175)					&						